OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS

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TABLE OF CONTENTS

Page

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

[1] This summary has been prepared by the FTC Health Care Division staff, and has not been reviewed or approved by the Commission or the Bureau of Competition. Section III describes FTC enforcement involving mergers in the pharmaceutical industry, which are primarily conducted by the Mergers I Division of the Bureau of Competition.

[2] Commission complaints and orders issued since March 1996 are available at the FTC's web site at http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

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.[4]

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

Mailing Address: Health Care Division
Bureau of Competition
Federal Trade Commission
Washington, DC 20580

Telephone Number: 202-326-2756
Fax Number: 202-326-3384

For further information about pharmaceutical mergers handled by the FTC's Mergers I Division, please write, call, or fax the Mergers I Division as follows:

Mailing Address: Mergers I Division
Bureau of Competition
Federal Trade Commission
Washington, DC 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*. The indices, the advisory opinions, and other information relating to the Commission's advisory opinion program are also available at the FTC's web site at http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

[4] *Statements of Antitrust Enforcement Policy in Health Care*, issued on August 28, 1996, 4 Trade Reg. Rep. (CCH) ¶13,153; *Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust*, issued on September 27, 1994, 4 Trade Reg. Rep. (CCH) ¶13,152; and *Department of Justice and Federal Trade Commission Antitrust Enforcement Policy Statements in the Health Care Area*, issued on September 15, 1993, 4 Trade Reg. Rep. (CCH) ¶13,151. The 1996 Policy Statements are available at http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.

II. CONDUCT INVOLVING PHARMACEUTICAL SERVICES AND PRODUCTS

A. Monopolization

Novartis AG, C-4296, FTC File No. 1010068 (consent order issued September 28, 2010) (http://www.ftc.gov/enforcement/cases-proceedings/101-0068/novartis-ag-matter). The Commission's complaint challenges Novartis AG's proposed $28.1 billion acquisition of Alcon, Inc., from Nestle, S.A. The complaint alleges that this acquisition would lessen competition in the $12.4 million U.S. market for injectable miotics – a class of prescription pharmaceuticals used to induce miosis (*i.e.*, constriction of the pupil), most commonly during cataract surgery. Novartis and Alcon each produces an injectable miotics product – Miochol-E and Miostat, respectively – for which there is no generic version. Novartis and Alcon are the only suppliers of injectable miotics in the U.S., with respective market shares of 67% and 33%. The complaint alleges that entry into the market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the acquisition because, in part, of lengthy FDA approval requirements and the fact that the market is small and in decline, with limited opportunities for new entrants. The consent order requires Novartis to divest its rights and assets in its injectable miotics product, Miochol-E, to Bausch & Lomb, Inc., an eye-health company that does not currently participate in the U.S. injectable miotics market.

Ovation Pharmaceuticals, Inc., FTC File No. 0810156 (http://www.ftc.gov/enforcement/cases-proceedings/081-0156/ovation-pharmaceuticals-inc-dba); **Federal Trade Commission v. Lundbeck, Inc.**, Civil No. 0:08-cv-06379-JNE-JJG (D. Minn.) (Findings of Fact, Conclusions of Law, and Order issued August 31, 2010). In December 2008, the Commission filed a complaint in the U.S. District Court for the District of Minnesota, challenging the purchase of the U.S. rights to NeoProfen – a drug for the treatment of patent ductus arteriosus ("PDA"), a potentially deadly heart defect affecting many premature infants – by Ovation (which was purchased in 2009 and renamed Lundbeck, Inc.). (The State of Minnesota also filed a complaint.) The Commission's complaint charges that the purchase eliminated Ovation's only competitor for the drug-based treatment of PDA, and thereby preserved Ovation's U.S. monopoly in the market for FDA-approved drugs to treat PDA. At the time of the purchase, NeoProfen was awaiting approval by the FDA. According to the complaint, Ovation expected that NeoProfen, once approved, would take a substantial portion of sales from Ovation's PDA drug, Indocin, and that Ovation acquired NeoProfen to eliminate this threat. The complaint charges that, after acquiring the rights to NeoProfen, Ovation raised the price of Indocin by nearly 1,300%; and when Ovation launched NeoProfen, it set the price at virtually the same level. At the time of the complaint, Ovation had maintained prices for the two drugs at or above this level for more than two years. The complaint charges that Ovation's acquisition of NeoProfen substantially raised prices, reduced competition, and maintained Ovation's monopoly in PDA drug treatments in violation of Section 7 of the Clayton Act and Section 5(a) of the FTC Act. The complaint seeks equitable relief, including divestiture and disgorgement of unlawfully obtained profits from Ovation's sales of Indocin and NeoProfen.

On August 31, 2010, the district judge held that the plaintiffs had not proved that NeoProfen and Indocin compete in the same product market, and, therefore, had failed to

demonstrate that the acquisition substantially lessened competition or maintained a monopoly. As a result, the court dismissed both actions.

Pfizer, Inc./Wyeth, C-4267, FTC File No. 0910053 (consent order issued January 25, 2010) (www.ftc.gov/os/caselist/0910053/index.shtm). The Commission's complaint challenges Pfizer's proposed $68 billion acquisition of Wyeth (particularly, Wyeth's "Fort Dodge" animal health division). Both firms manufacture human and animal health biological and pharmaceutical agents. The combined firm would have projected worldwide revenues of almost $72 billion. The complaint charges that the acquisition would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by reducing competition in the following 21 U.S. markets for animal health products:

■ *Cattle Health Product Markets.* Pfizer and Wyeth's Fort Dodge animal health division are the market leaders in the area of cattle health products. After the acquisition, Pfizer would have over 60 percent of several relevant cattle health product markets.

- *Killed cattle respiratory vaccines* prevent respiratory diseases in pregnant cattle without the risk of causing abortion. Pfizer and Fort Dodge account for over 50 percent of all killed respiratory vaccine sales in the U.S. As a result of the acquisition, Pfizer would control 61 percent of the market for 5-way vaccine (the most commonly used killed respiratory vaccine), leaving only one other significant competitor in this $15.3 million market.

- *Modified-live cattle respiratory vaccines* prevent the same diseases as killed respiratory vaccines, but contain modified-live, rather than killed, antigens to stimulate greater protection. Because they induce stronger immunities, most customers will use modified-live vaccines for non-pregnant cattle. Pfizer and Fort Dodge account for over 53 percent of all modified-live respiratory vaccine sales in the $63 million U.S. market. As a result of the acquisition, Pfizer would control over 68 percent of the market for 5-way vaccine (the most commonly used modified-live respiratory vaccine).

- *Cattle reproductive vaccines* are used to prevent abortions in pregnant cattle. The most significant markets for these vaccines include the markets for: (1) modified-live 10-way vaccines; (2) killed 10-way vaccines; and (3) lepto/vibrio vaccines. After the acquisition, Pfizer would control 83 percent of the $13 million U.S. market for modified-live 10-way vaccine, with the remaining 17 percent of the market divided among three other firms. Pfizer would also control 76 percent of the U.S. market for killed 10-way vaccine, with the rest of that market divided between two firms. Pfizer would also control almost 39 percent of the lepto/vibrio market, with another firm at 41 percent.

- *Cattle pasteurella vaccines* are used to prevent pneumonia and other respiratory infections in cattle caused by certain bacteria. The proposed acquisition would reduce the number of competing firms in the U.S. market from five to four, and would leave Pfizer significantly larger than any of its remaining competitors.

- *Lactating-cow and dry-cow mastitis treatments* are used to treat infections of the udder that occur either during lactation or between pregnancies. The markets for these treatments are highly concentrated, and the proposed acquisition would give Pfizer control of over 90 percent of each market.

- *Dairy cattle broad-spectrum antibiotics with low milk-withholding times* (*i.e.,* an FDA-mandated waiting period between the administration of the antibiotic and the time when milk from the affected cattle may be distributed for sale) are used to treat a variety of infections that affect dairy cattle. Pfizer and Fort Dodge products have very low withholding times (zero days and two-to-four days, respectively). A generic version of one of Pfizer's products was recently introduced. The proposed acquisition would reduce the number of firms selling these antibiotics in the U.S. market from three to two, and would give Pfizer a near monopoly in this $162 million market.

- *Cattle macrocyclic lactone parasiticides* are the newest and most effective class of cattle parasiticides in the U.S. There are three companies producing branded products in this $118 million market: Pfizer, Fort Dodge, and Merial. Generic versions of Merial's (but not Pfizer's or Fort Dodge's) product are available, but do not provide a significant competitive restraint due to their poor reputation in this market. The proposed acquisition would increase the concentration in this market significantly, leaving Pfizer with about 42 percent of the market.

- *Cattle benzimidazole parasiticides* are an older generation of drugs used to treat internal parasites such as lugworms, tapeworms, and liver flukes. The proposed transaction would reduce the number of suppliers of these parasiticides in the $16 million U.S. market from three to two, and would increase Pfizer's market share to 33 percent.

■ *Companion Animal Health Product Markets.* Pfizer and Fort Dodge are two of only four major suppliers in the relevant companion animal vaccines and pharmaceuticals markets. In most of these markets, the proposed acquisition would reduce the number of competitors from four to three, and give Pfizer control of between 50 and 100 percent of the market. Pfizer and Fort Dodge have broad and significantly overlapping portfolios of companion animal health products.

- *Canine combination vaccines* prevent common canine diseases, such as those caused by canine distemper, adenovirus, parainfluenza, parvovirus, and coronavirus. The proposed acquisition would reduce the number of significant suppliers of canine combination vaccines in the U.S. from four to three in this $126 million market.

- *Canine monovalent parvovirus vaccines* are administered as booster shots to puppies for many of the diseases treated by canine combination vaccines. The proposed acquisition would reduce the number of suppliers of this vaccine in the U.S. from four to three in this $2.1 million market, and would give Pfizer control of 66 percent of the market.

- *Canine monovalent coronavirus vaccines* represent a $2.3 million market in the U.S. The proposed acquisition would reduce the number of suppliers of this vaccine from four to three, and would leave Pfizer with an 81 percent share of the market.

- *Canine monovalent leptospira vaccines* represent a $9.2 million market in the U.S. Pfizer and Fort Dodge are currently the only two suppliers of this vaccine. The proposed transaction would give Pfizer control over 100 percent of this market.

- *Canine bordetella vaccines* are used primarily to treat the most common form of upper respiratory infection contracted by dogs in the U.S. The proposed acquisition would reduce the number of suppliers of these vaccines from five to four, and would leave Pfizer with a significantly larger share of this $53.3 million market than its three remaining competitors.

- *Feline combination vaccines* are used to prevent common feline diseases, such as feline panleukopenia, rhinotracheitis, chlamydia, and calcivirus. There are four significant suppliers of these vaccines in the $28 million U.S. market. The proposed acquisition would reduce the number of suppliers of these vaccines from four to three, and would leave Pfizer with a considerably larger share of this market than its two remaining competitors.

- *Feline leukemia vaccines* provide protection against feline leukemia, a fatal disease that breaks down a cat's immune system and leaves it vulnerable to other diseases. There are four companies that supply these vaccines in the $38 million U.S. market. The proposed acquisition will reduce the number of suppliers of these vaccines from four to three, and leave Pfizer with a significantly larger market share than its two remaining competitors.

- *Companion animal rabies vaccines* are used to prevent rabies. The proposed transaction would reduce the number of suppliers in this $60 million U.S. market from four to three.

- *Companion animal cephalosporins* are a recent generation of broad-spectrum antibiotics that can be used to treat a wide range of infections. Pfizer and Fort Dodge are the only two suppliers of branded companion animal cephalosporins in the $52 million U.S. market. While there are generic human and animal cephalosporin products in the market, they have limited competitive significance because of dosing differences found in the generic human products and a relative lack of technical and research support offered with the generic animal products. The proposed acquisition would give Pfizer control of 70 percent of this market.

■ *Equine Health Product Markets.*

- *Equine tapeworm parasiticides containing praziquantel* are used to treat tapeworms and other internal parasites, which are the leading cause of equine colic. The proposed acquisition would reduce the number of suppliers of these parasiticides in the $22 million U.S. market from three to two, and would give Pfizer control of 64 percent of the market.

- *Equine herpesvirus vaccines* are used primarily to prevent equine rhinopneumonitis, an upper respiratory disease that can cause abortions in pregnant mares. The proposed acquisition would reduce the number of suppliers of these vaccines in the $30 million U.S. market from four to three, leaving Pfizer significantly larger than its two remaining competitors.

- *Equine joint-injected steroids* can be used to treat joint inflammation, osteoporosis, and lameness in horses. Pfizer and Fort Dodge are the only two providers of these steroids in the $7.3 million U.S. market. The proposed acquisition would leave Pfizer with 100 percent of the market.

The complaint states that entry into the manufacture and sale of the relevant markets would not be timely, likely, or sufficient to counteract the anticompetitive effects of the proposed acquisition, due to, among other things, research and development costs, regulatory hurdles, and the need to gain customer acceptance. The complaint also charges that the proposed acquisition would cause significant competitive harm to consumers in the relevant markets by: eliminating actual, direct, and substantial competition between Pfizer and Wyeth; increasing the likelihood that Pfizer could unilaterally exercise market power; increasing the likelihood of coordinated action between suppliers; reducing Pfizer's incentives to pursue further research and development; and increasing the likelihood that consumers will pay higher prices. The consent order requires that Pfizer divest the Fort Dodge U.S. animal health products business in all areas of overlap (except for equine tapeworm parasiticides and equine herpesvirus vaccines) to Boehringer Ingelheim Vetmedica, Inc. In the area of equine tapeworm parasiticides, Pfizer is ordered to return Pfizer's exclusive distribution rights to these products to Virbac S.A. In the area of equine herpesvirus vaccines, Pfizer is ordered to divest Pfizer's equine herpesvirus vaccine products to Boehringer. The assets for each of these divestitures include all of the relevant intellectual property, customer lists, research and development information, and regulatory materials, as well as two of Fort Dodge's three U.S. manufacturing facilities. These divestitures will fully preserve the competition that the proposed acquisition would eliminate.

Schering-Plough Corporation/Merck & Co., Inc., C-4268, FTC File No. 0910075 (consent agreement accepted for public comment; consent order issued October 29, 2009) (www.ftc.gov/os/caselist/0910075/index.shtm). The Commission's complaint challenges Schering's proposed $41.1 billion acquisition of Merck. Merck and Schering both supply a variety of human and animal health products. Merck's animal health products business is carried on through Merial Limited, an equally-owned joint venture of Merck and Sanofi-Aventis S.A. The complaint charges that the acquisition would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by lessening competition in the following U.S. markets:

- *Neurokinin 1 ("NK1") receptor antagonists* for chemotherapy-induced nausea and vomiting ("CINV") and post-operative nausea and vomiting ("PONV") in humans. Merck's Emend is the only NK1 receptor antagonist for CINV and PONV in the U.S. At the time the proposed acquisition was announced, Schering was in the process of out-licensing rolapitant, an NK1 receptor antagonist for CINV and PONV that Schering had been developing – one of a very limited number of such drugs in development for the U.S. market. The proposed acquisition

would likely reduce the combined firm's incentive to license rolapitant, which would compete with Emend.

■ *Live poultry vaccines* and *Killed poultry vaccines* for the prevention or treatment of: (1) each strain of Marek's disease; (2) each strain of infectious bronchitis; (3) Newcastle disease; (4) each strain of infectious bursal disease; (5) reovirus; (6) fowl pox; (7) coccidiosis; (8) lanyngotracheitis; (9) avian encephalomyelitis; and (10) tenosynovitis. Merck (through Merial) and Schering are the two largest producers of poultry vaccines in the U.S. Together, Merial and Schering account for over 75 percent of all poultry vaccine sales in the U.S. Three other suppliers account for the balance of U.S. poultry vaccine sales.

■ *Cattle gonadotropins*. These products are used to treat follicular cysts in cattle, and to synchronize the reproductive cycles of cattle undergoing artificial insemination. Merck (through Merial) and Schering are two of only three suppliers of cattle gonadotropins in the U.S. market.

The consent order requires Merck to divest all of its interest in Merial to its joint venture partner, Sanofi-Aventis. This sale was completed in September 2009, at the same time terminating the Merial joint venture. In order to ensure that the combined Merck/Schering and Sanofi-Aventis do not combine their animal health businesses after the divestiture, the order prohibits Merck from acquiring any of Merial's animal health assets, or otherwise combining the animal health businesses of Merck and Sanofi-Aventis, without prior approval of the Commission. The order also requires Schering to divest all of the assets relating to its NK1 receptor antagonist, rolapitant, to Opko Health, Inc. In order to ensure that this divestiture is successful, the order requires Schering and Merck to provide transitional services to enable Opko to complete clinical testing and obtain regulatory approval to market rolapitant in the U.S. The order also allows the Commission to appoint an Interim Monitor to ensure that the parties fulfill their obligations relating to the divestiture.

The Commission issued the complaint and order, and served them upon Merck and Schering at the same time it accepted the consent agreement for public comment. As a result, the order became effective immediately. *See* 16 C.F.R. § 2.34(c). This matter represents an "exceptional case" (64 Fed. Reg. 46267 (1999)) in which it is appropriate to issue a final order before receiving public comment, because of the risk that the combined Merck/Schering and Sanofi-Aventis might combine their animal health businesses after the proposed acquisition was consummated, and thereby reverse the animal health remedy of the consent agreement.

CSL Limited/Cerberus-Plasma Holdings, LLC, D. 9337, FTC File No. 0812255 (administrative complaint issued May 27, 2009) (http://www.ftc.gov/enforcement/cases-proceedings/081-0255/csl-limited-corporation-cerberus-plasma-holdings-llc-matter); Case No. 09-cv-1000-CKK (D.D.C. May 29, 2009) (motion for preliminary injunction filed) (http://www.ftc.gov/enforcement/cases-proceedings/081-0255/csl-limited-corporation-cerberus-plasma-holdings-llc-matter); (CSL announced that it will not proceed with the proposed acquisition, June 8, 2009) (http://www.ftc.gov/news-events/press-releases/2009/06/statement-ftcs-bureau-competition-regarding-announcement-csl-will). The complaint seeks to block CSL

Limited's proposed $3.1 billion acquisition of Talecris Biotherapeutics Holdings Corp. (a wholly owned subsidiary of Cerberus-Plasma Holdings, LLC). (The Commission also sought a preliminary injunction in federal court, to halt the transaction pending the outcome of the administrative trial.) The complaint charges that the proposed acquisition would substantially lessen competition in the U.S. markets for four plasma-derivative protein therapies: Immune globulin (Ig); Albumin; Alpha-1; and Rho-D. The complaint further alleges that the effect will be further tightening of supply relative to demand and steeper price increases – potentially depriving critically ill patients of needed treatments (which can cost more than $90,000 annually per patient). CSL is the world's second-largest supplier of plasma-derivative protein therapies. CSL owns and operates more than 70 plasma collection facilities in the U.S. and Germany, and three manufacturing facilities in Europe and the U.S. Talecris is the world's third-largest producer of plasma-derivative protein therapies. Like CSL, Talecris owns a number of plasma collection centers, as well as two manufacturing facilities, in the U.S. The complaint states that the plasma-derivatives products industry has become much more concentrated since 1990 (from 13 firms to five), and has resulted in an oligopolistic industry wherein competition has been greatly curtailed. The complaint charges that the proposed acquisition would have further anticompetitive effects in each of the following markets:

- *IG* and *Albumin*. IG is a widely-prescribed drug, used most commonly to treat primary immunodeficiency diseases and certain neurological conditions. IVIG, the predominant form of IG, has over 20 FDA-approved indications, and as many as 150 off-label uses. Albumin is used as a blood volume expander and to prime heart valves during surgery. There are no good substitutes for IG or Albumin. The acquisition would decrease the number of firms in these markets from five to four (with two of the remaining firms being too small to have a significant market impact). In each market, following the proposed acquisition, the combined firm would control nearly 50 percent of the market. Moreover, Talecris has been a unique competitive restraint in these markets, and so its elimination would be particularly detrimental to competition. The acquisition would substantially lessen competition by enabling the remaining firms in these markets to engage more completely and successfully in coordinated interaction that harms consumers.

- *Alpha-1*. Alpha-1 is FDA-approved to treat alpha-1 antitrypsin deficiency-related lung disease. There are no good substitutes. The acquisition would reduce the number of competitors in this market from three to two. Talecris has been a vigorous competitor in this market for the past five years. The acquisition would leave the combined CSL/Talecris with a market share of over 80 percent, and would eliminate the existing vigorous competition. The two remaining firms in this market would then be able to coordinate more completely and successfully on price.

- *Rho-D*. Rho-D is used to prevent hemolytic disease in newborns. There are no good substitutes. The acquisition would reduce the number of competitors in this market from three to two. Talecris has been one of two relatively low-price suppliers of Rho-D, and its elimination would likely end that vigorous price competition. The acquisition would leave the combined CSL/Talecris with a 40 percent market share. The two remaining firms in this market would be able to coordinate more completely and successfully on price.

The complaint also charges that there are significant regulatory, intellectual property, and capital requirements in these markets that make entry or expansion unlikely to occur to a degree sufficient to offset the anticompetitive effects of the proposed acquisition. Following the Commission's filing of its administrative complaint and the preliminary injunction lawsuit, CSL announced that it will not proceed with the proposed acquisition of Talecris.

Inverness Medical Innovations, Inc., C-4244 (consent order issued January 23, 2009) (http://www.ftc.gov/enforcement/cases-proceedings/061-0123/inverness-medical-innovations-inc-matter). The complaint charges that Inverness – the dominant firm in the U.S. market for consumer pregnancy tests, with a 70 percent market share – unreasonably restrained competition through its acquisition of certain assets of ACON Laboratories, Inc. (ACON), a competing producer of consumer pregnancy tests. In 2006, Inverness acquired a consumer pregnancy test based on water-soluble dye technology that ACON was developing, as well as assets related to a digital consumer pregnancy test joint venture between ACON and another company, Church & Dwight. The complaint charges that these acquisitions unreasonably restrained competition in two ways. First, Inverness limited potential competition from digital consumer pregnancy test products by, among other things: (1) imposing a covenant not to compete on ACON, which limited the scope and duration of its joint venture with Church & Dwight; (2) requiring ACON to provide Inverness with all profits from the joint venture; and (3) acquiring rights to certain intellectual property developed by ACON and Church & Dwight during their joint venture. Second, Inverness engaged in unfair competition to maintain its monopoly in the consumer pregnancy test market when it bought, but did not use, ACON's water-soluble dye technology assets, because the acquisition of these assets solidified Inverness' monopoly, and kept that technology from being developed into products that would compete with Inverness' consumer pregnancy tests. The consent order contains provisions to prevent Inverness from interfering with the ACON-Church & Dwight joint venture, and to enable those firms to remain competitively viable after the joint venture ends. The order also requires Inverness to divest assets related to ACON's water-soluble dye technology to Aemoh Products, Inc. The order also prohibits Inverness from making infringement claims against certain products that use its water-soluble dye technology.

Cephalon, Inc., Civil Action No.: 1:08-cv-00244 (D.D.C.) (complaint filed February 13, 2008) (http://www.ftc.gov/os/caselist/0610182/index.shtm). The Commission filed a complaint in U.S. District Court for the District of Columbia seeking a permanent injunction against Cephalon for engaging in an overall course of anticompetitive conduct to prevent generic competition to Provigil, a drug used to treat sleep disorders, and which accounted for more than 40% of Cephalon's total sales. The complaint alleged that four generic manufacturers (all considered first filers by the FDA for generic Provigil) were involved in patent litigation over the only remaining patent covering Provigil, and Cephalon paid the generic manufacturers over $200 million dollars to abandon the patent litigation and agree to refrain from selling a generic version of Provigil until 2012. According to the complaint, the agreements not only prevented competition from the four first filers but also blocked competition from other generic manufacturers because of the 180-day exclusivity held by the first filers under the Hatch-Waxman Act. As a result of the agreements, Cephalon denied consumers access to lower-cost

generic versions of Provigil and forced consumers to pay hundreds of millions of dollars more a year than they would have if generic Provigil entered the market. The Commission is asking the Court to order that Cephalon's conduct, including entering into the agreements, violates Section 5 of the FTC Act. The Commission is also asking the Court to order a permanent injunction stopping Cephalon from enforcing or maintaining the agreements, and enjoining Cephalon from engaging in similar conduct in the future.

Bristol-Myers Squibb Company, 135 F.T.C. 444 (2003) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume135.pdf#page=449). The Commission charged in its complaint that Bristol engaged in a pattern of anticompetitive activity over the past decade in order to delay generic competition and maintain its monopoly over three highly profitable branded drugs with total net annual sales of two billion dollars. As a result of Bristol's illegal conduct, consumers paid hundreds of millions of dollars in additional costs for these prescription drugs. The drugs named in the complaint were the anti-anxiety drug, BuSpar, and two anti-cancer drugs, Taxol and Platinol. The pattern of illegal activity involved misusing regulations set up by Congress to hasten the approval of generic drugs, misleading the FDA and the U.S. Patent and Trademark Office in order to protect patents on these branded drugs, and filing baseless patent infringement lawsuits against would be generic competitors. As detailed in the complaint, the anticompetitive activities involving BuSpar included: paying a would-be generic competitor $72.5 million to settle patent litigation, thereby preventing the introduction of a generic BuSpar; filing false information with the FDA in order to list a patent in the Orange Book, thereby automatically obtaining additional 30-month stays; and filing baseless patent infringement suits against potential generic competitors. The complaint alleged that Bristol engaged in similar types of activities with Taxol, a chemotherapy drug originally developed and funded by the National Cancer Institute, which had given Bristol exclusive marketing rights. This conduct including improperly listing three patents in the Orange book, filing misrepresentative statements with the FDA, and entering into an unlawful agreement with a generic competitor in order to obtain an additional 30-month stay on FDA approval of generic Taxol. Similarly, according to the complaint, Bristol engaged in the same type of unlawful activities involving another chemotherapy drug, Platinol, that also included wrongfully submitting a patent for listing in the Orange Book, and filing patent infringement lawsuits against each of four potential generic entrants, resulting in the delay of a generic Platinol.

The order contains general prohibitions concerning conduct relating to Orange Book listings (detailed in the Commission's recent study, *Generic Drug Entry Prior to Patent Expiration*), enforcement of patents, and the settlement of patent litigation when that conduct is designed to delay or prevent generic competition. For example Bristol is prohibited from late listing patents after competitors have filed applications with the FDA for generic entry. The order also contains prohibitions relating specifically to the listing and enforcement of patents relating to Taxol and BuSpar, including listing any patent in the Orange Book relating to products with the same active ingredient, or taking any action that would trigger an additional 30-month statutory stay on final FDA approval of a generic form of Taxol or BuSpar (the order does not provide specific relief for Platinol because a court held the only unexpired patent on Platinol was invalid).

Biovail Corporation, 134 F.T.C. 407 (2002) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume134.pdf#page=411). The complaint charged that Biovail illegally acquired the exclusive license to a drug patent in order to prevent generic competition from ending its monopoly in the antihypertension drug Tiazac. Biovail then wrongfully listed the acquired patent as claiming Tiazac in the FDA's Orange Book in order to maintain its monopoly. As a result of the Orange Book listing and other conduct, including making a misleading statement to the FDA during the regulatory process, the complaint alleged that Biovail sought to illegally delay the entry of generic Tiazac by gaining a second 30-month stay on generic entry through patent infringement litigation. The order requires Biovail to divest part of the exclusive rights of the acquired patent back to DOV Pharmaceuticals, the original owner. In addition, the order prohibits Biovail from taking any action that would trigger an additional statutory stay on final FDA approval of a generic form of Tiazac. The order also prohibits Biovail from wrongfully listing any patents in the Orange Book.

Mylan Laboratories et al., 62 F. Supp. 2d 25 (D.D.C. 1999) (http://www.ftc.gov/enforcement/cases-proceedings/9810146/mylan-laboratories-inc-cambrex-corporation-profarmaco-sri-gyma). 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 and conspiracy to monopolize the markets for two generic anti-anxiety drugs, lorazepam and clorazepate. The complaint also charged Mylan with monopolization and attempted monopolization of those markets. Thirty four state Attorneys General filed a similar complaint in U.S. District Court. 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 clorazepate tablets, thereby allowing Mylan to dramatically increase the price of lorazepam and clorazepate tablets. 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. On November 29, 2000, the Commission approved a proposed settlement, subject to approval by the federal district court, under which Mylan agreed to pay $100 million for distribution to injured consumers and state agencies. The defendants also agreed to an injunction barring them from entering into similar unlawful conduct in the future. Fifty states and the District of Columbia also approved the agreement. In a separate statement, Commissioner Leary dissented regarding the financial aspects of the settlement because of his concern that it sets an undesirable precedent for use of the Section 13(b) remedy in federal and state antitrust enforcement, and conflicts with the holding in Illinois Brick concerning the ability of indirect purchasers to claim damages. In a separate statement, Commissioners Pitofsky, Anthony, and Thompson agreed with the need to use discretion in seeking disgorgement in future antitrust cases, but stated that the decision to seek disgorgement in this case was appropriate and consistent with policy considerations towards indirect purchasers raised by Illinois Brick. On February 9, 2001, the court entered the Stipulated Permanent Injunction agreed to by the parties. On February 1, 2002, the court granted final approval of the settlement agreement and distribution plan under which Mylan was required

to place $100 million into an escrow account for disbursement to purchasers of lorazepam and/or clorazepate during the time period covered by the settlement.

B. Agreements Not to Compete

Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al. ("Generic Androgel"), CV-09-00598 (civil complaint filed in U.S. District Court for the Central District of California, January 27, 2009), FTC File No. 0710060. **In Re: Androgel Antitrust Litigation (No. II)**, MDL Docket No. 2084 (All Cases), 1:09-MD-2084-TWT, 677 F.3d 1298 (11th Cir. 2012) (affirming lower court's order granting motions to dismiss complaints). **Federal Trade Commission v. Actavis,** (petition for *certiorari* granted December 7, 2012; Supreme Court oral argument scheduled for March 25, 2013) (http://www.ftc.gov/enforcement/cases-proceedings/071-0060/watson-pharmaceuticals-inc-et-al).

In January 2009, the FTC, joined by the State of California, filed a civil complaint in U.S. district court against Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., and Solvay Pharmaceuticals, Inc. The complaint challenged agreements in which Solvay allegedly paid generic drug makers Watson and Par to delay generic competition to Solvay's branded testosterone-replacement drug AndroGel. AndroGel has consistently been Solvay's best-selling product, with 2007 sales of over $400 million, accounting for about one-third of Solvay's U.S. revenues. The complaint charged that Watson and Par (through its partner Paddock) each sought FDA approval in 2003 to market generic versions of AndroGel. Both firms certified in their FDA filings that their generic products did not infringe the only patent Solvay had relating to AndroGel, and that the patent was invalid. The patent's expiration date was in August 2020. Watson received FDA final approval to market its generic product in early 2006. The complaint charged that the defendants knew that, if Watson or Par were to enter the market with less expensive generic versions of AndroGel, Solvay's AndroGel sales would plummet and consumers would benefit from the lower prices. The complaint charged that Solvay acted unlawfully to eliminate this threat, by paying Watson and Par a share of its AndroGel profits in exchange for abandoning their patent challenges and agreeing to delay generic entry until 2015. As a result, the complaint charged, the three companies are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing. The complaint further charged that potential competition was harmed because of the elimination of two potential competitors; and that consumers were harmed by being forced to pay higher prices for AndroGel than for generic versions of that drug. The Commission sought a judgment declaring that Solvay's agreements with Watson and Par (and Paddock) violate Section 5(a) of the FTC Act, and injunctive relief restoring competitive conditions and barring the defendants from engaging in similar or related conduct in the future.

A number of private parties also filed antitrust actions against Solvay, Watson, Par, and Paddock. These actions, along with the Commission's lawsuit, were transferred to the U.S. District Court for the Northern District of Georgia. The defendants filed motions to dismiss these complaints. In February 2010, the district court granted these motions to dismiss as to the complaints of the Commission and certain private plaintiffs, and granted in part and denied in part those motions as to the complaints of other private plaintiffs. Relying primarily on Valley

Drug Co. v. Geneva Pharms, Inc., 344 F.3d 1294 (11th Cir. 2003), the court decided, *inter alia*, that the arguments of the Commission and other plaintiffs were inconsistent with that decision. On June 10, 2010 the Commission appealed to the U.S. Court of Appeals for the Eleventh Circuit, and the court upheld the District Court's ruling on April 24, 2012. At the FTC's request, the Solicitor General of the United States filed a petition for *certiorari* with the U.S. Supreme Court on October 4, 2012 requesting review of the federal appeals court's decision. The Supreme Court granted *certiortari* on December 7, 2012, and oral argument is scheduled for March 25, 2012.

Federal Trade Commission v. Bristol-Myers Squibb Company, Civ. No. 09-0576 (D.D.C. March 30, 2009) (final judgment) (http://www.ftc.gov/enforcement/cases-proceedings/0610235/bristol-myers-squibb-company). A U.S. District Court judgment requires drug manufacturer Bristol-Myers Squibb Company (BMS) to pay a $2.1 million civil penalty for violating its reporting requirements under the Medicare Modernization Act[5] (MMA) and for violating the terms of a 2003 FTC consent decree. The 2003 consent decree settles charges that BMS had entered into agreements with potential generic drug manufacturers to delay their entry into the market in exchange for payments from BMS, and requires BMS to submit certain future drug settlement agreements to the Commission for review. The MMA also requires that certain drug company agreements be reported to both the FTC and the U.S. Department of Justice (DOJ).

According to the complaint, in 2006 BMS and Apotex entered a patent settlement, in which, among other things, BMS granted Apotex a license to sell a generic version of Plavix, and BMS agreed not to launch, or authorize any other party to launch, its own generic version of Plavix during the first six months of the license. BMS's agreement not to launch an authorized generic for six months could be of significant value to Apotex, because it would make the Apotex product the only generic available during that period. BMS submitted the proposed agreement to the FTC for review, as required by the 2003 order; and both BMS and Apotex filed in accordance with the MMA. When Commission staff raised concerns regarding BMS's agreement not to launch an authorized generic for six months, BMS withdrew its submission, executed a revised settlement with Apotex, and then submitted the revised proposed settlement to the FTC. This revised proposed settlement agreement omitted the mention of any promise by BMS not to launch an authorized generic during the first six months of the Apotex license. In Apotex's submission of the revised proposed settlement agreement, it informed the FTC that BMS had made certain oral representations in addition to those included in the written revised settlement agreement.

Upon request by Commission staff, BMS submitted a certification, under oath, that it had not represented to Apotex that BMS would refrain from launching an authorized generic version of Plavix during the first six months of the Apotex license. Apotex later submitted additional materials, including a sworn declaration, confirming its position that BMS had made additional oral representations. Faced with conflicting sworn statements, the Commission opened a non-

[5] Title XI, Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173, 117 Stat. 2461 (Dec. 8, 2003).

public investigation, and informed the DOJ of the conflicting declarations. Upon investigation, DOJ filed criminal charges against BMS and a former BMS executive, Dr. Andrew G. Bodner. Ultimately, BMS pled guilty to two counts of perjury and subsequently paid $1 million in fines (the maximum penalty for the two counts) for, among other things, failing to disclose its representations to Apotex that BMS would not launch an authorized generic. Dr. Bodner also pleaded guilty to making a false statement to the government and was fined and sentenced to two years of probation. The Commission then sued BMS for violation of the 2003 consent order and the MMA, and sought civil penalties. The $2.1 million civil penalty judgment in this case represents the maximum statutory penalty available for BMS's civil violations.

Warner Chilcott Corporation/Barr Pharmaceuticals, Civil Action No. 1:05-CV-2179-CKK (D.D.C) (complaint filed November 7, 2005, amended complaint filed December 2, 2005) (http://www.ftc.gov/os/caselist/0410034/0410034.htm). The Commission filed a complaint in U.S. District Court for the District of Columbia seeking an injunction against an agreement entered into by Warner Chilcott and Barr to prevent entry of Barr's generic version of Warner Chilcott's highly profitable Ovcon 35 oral contraceptive. Under the March, 2004 agreement, Warner Chilcott agreed to pay Barr $20 million in exchange for Barr's delaying entry of its generic version of Ovcon for five years. According to the complaint, Warner Chilcott expected to lose 50% of its net sales of $71 million earned from branded Ovcon upon entry of a generic. Barr filed an application in 2001 with the FDA to make and sell a generic version of Ovcon, and at the beginning of 2003, Barr announced its intention to market its generic version of Ovcon by the end of the year. After Barr received FDA approval to make and sell its generic version of Ovcon in April 2004, Warner Chilcott paid Barr the $20 million, thus preventing Barr from selling a generic version of Ovcon until May 2009. The Commission filed a preliminary injunction on September 25, 2006, after it learned that Warner Chilcott was planning to launch a new chewable version of Ovcon, switch patients over to the new product, and then stop selling Ovcon. Because generic substitution would be unavailable if regular Ovcon was no longer available at the pharmacy, this switch strategy would have destroyed the market for generic Ovcon. Shortly after the Commission filed the request for a preliminary injunction, Warner Chilcott abandoned the provision in the 2004 agreement that prevented Barr from entering the market with its generic version, and Barr launched its generic version. Warner Chilcott also agreed to a settlement in which it agreed not to enter into any supply agreements with generic manufacturers in which the generic agrees not to compete with Warner Chilcott. The agreement also prohibits Warner Chilcott from entering into any agreement where Warner Chilcott provides the generic with anything of value, the generic refrains from research development, manufacturing, marketing, distribution or sale of a generic version, and the agreement adversely affects competition. The district court entered a final order settling the matter with Warner Chilcott on October 23, 2006. On November 2007, the court entered a final order settling the Commission's complaint against Barr. The Commission's settlement agreement with Barr forbids Barr from entering into anticompetitive supply agreements with branded companies, similar to the agreement with Warner Chilcott discussed above, and any anticompetitive agreements with branded manufacturers in which Barr receives monetary compensation or agrees to limit the research, development, manufacturing, marketing, distribution of the generic product. The agreement also requires Barr to give the Commission prior notification for ten

years if Barr enters into any other agreements with branded manufacturers that have the potential to harm competition.

Perrigo Company/Alpharma Inc., Civil Action No. 1:04CV01397 (RMC) (D.D.C.) (complaint filed August 17, 2004) (http://www.ftc.gov/enforcement/cases-proceedings/0210197/perrigo-company-alpharma-inc-ftc). In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged two generic drug manufacturers, Alpharma, Inc. and Perrigo Company, with entering into an agreement to limit competition for over-the-counter store-brand children's liquid Ibuprofen. The two companies were the only manufacturers of over-the-counter store-brand children's liquid Ibuprofen approved by the FDA. Fifty state attorneys general also filed a similar complaint in U.S. District Court. According to the FTC's complaint, Perrigo and Alpharma agreed to allocate to Perrigo the sale of over-the-counter store-brand children's liquid Motrin for seven years, in return for an up-front payment and a royalty on Perrigo's sales of the drug. Both parties projected that prices would rise 25% if they allocated the market. As a result of the agreement, Perrigo raised its prices to those customers who had negotiated lower prices when the two companies were competing. On August 25, 2004, the court granted final approval of settlement agreements under which Alpharma and Perrigo were required to disgorge $6.25 of illegal profits for disbursement to consumers harmed by the illegal agreement. The settlement agreements also forbid the defendants from entering into agreements not to compete where one party is the first filer of an abbreviated new drug application with the FDA.

Bristol-Myers Squibb Company (See Section I A for citation and annotation.)

Biovail Corporation/Elan Corporation, 134 F.T.C. 302 (2002) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume134.pdf#page=306). According to the complaint, Biovail and Elan were the only companies with FDA approval to market 30 mg and 60 mg generic Adalat. Elan was the first to file for FDA approval on the 30 mg dosage, and Biovail was the first to file for FDA approval on the 60 mg dosage. Pursuant to the Hatch-Waxman Act, Elan qualified for 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail qualified for 180 days of exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the dosage for which the other was the first filer. Prior to generic entry, Bayer's sales of the branded form of the 30 mg and 60 mg products were in excess of $270 million a year. In October 1999, Biovail and Elan entered into an agreement involving these products. In exchange for specified payments, Elan appointed Biovail as the exclusive distributor of Elan's 30 mg and 60 mg products and allowed Biovail to profit from the sale of both products. Biovail appointed Teva Pharmaceuticals, Inc. to sub-distribute Elan's 30 mg product in the United States, and agreed to appoint another firm to sub-distribute Elan's 60 mg product. The agreement had a minimum term of 15 years.

In March 2000, the FDA gave final approval to Elan's 30 mg product and Elan, under its agreement with Biovail, entered the market with its 30 mg product through Biovail. In December 2000, the FDA gave final approval to Biovail's 60 mg product and Biovail entered the market with that product. Also in December 2000, the FDA gave final approval to Biovail's 30 mg product, but Biovail never launched that product. Similarly, in October 2001, the FDA gave

final approval to Elan's 60 mg product, but Elan never launched that product. Thus, Elan had a monopoly over 30 mg generic Adalat, the profits from which it shared with Biovail; Biovail had a monopoly over 60 mg generic Adalat, having paid Elan a multi-million dollar royalty; and neither launched a product in competition with the other's dosage form.

The order requires Biovail and Elan to terminate their agreement immediately, and prohibits them from entering similar agreements in the future. It requires them to use best efforts to effect independent launches of both 30 mg and both 60 mg generic Adalat products as promptly as possible, and contains an interim supply arrangement to ensure that consumers continue to have access to at least one 30 mg and one 60 mg product while Biovail and Elan unwind their agreement. In addition, the order contains strict reporting and notice requirements intended to assist the Commission in monitoring compliance with the order.

Schering-Plough Corporation, et. al., D. 9297, Initial Decision issued June 27, 2003, rev'd by Commission Decision and Order, December 8, 2003 (136 F.T.C. 956 (2003)) (http://www.ftc.gov/os/decisions/docs/Volume136.pdf#page=961); rev'd 402 F.3d 1056 (11th Cir. 2005); order denying rehearing *en banc* issued May 31, 2005 (Pet. App. 36a-153a (unreported); Petition for Certiorari filed August, 2005. The complaint alleged that Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products Corporation entered into anticompetitive agreements in which Schering paid Upsher and American Home Products millions of dollars to forgo launching a competitive generic alternative to K-Dur 20, an extended-release potassium chloride supplement manufactured by Schering. Schering sued Upsher, a generic drug manufacturer, for patent infringement after Upsher sought FDA approval to manufacture and distribute Klor Con M20, a generic version of K-Dur 20. According to the complaint, Schering and Upsher reached an agreement in 1997 to settle the patent infringement lawsuit, whereby Schering paid Upsher $60 million dollars and Upshur agreed not to market any generic version of K-Dur 20 until September, 2001. Under the agreement, Schering received licenses to market five of Upsher's products but, the complaint charged, Schering paid Upsher to secure it's agreement to the 2001 entry date, and the effect of the agreement was to ensure that no other company's generic K-Dur 20 could obtain FDA approval and enter the market during the term of the agreement.

The complaint also alleged that Schering agreed to pay ESI Lederle, Inc., a division of American Home Products, to forgo marketing its generic version of K-Dur 20, in connection with settlement of patent infringement litigation. American Home Products agreed to a proposed consent agreement, and on April 2, 2002, the Commission approved a final order settling the charges against American Home Products. (see American Home Products discussed below).

After an administrative trial as to respondents Schering and Upsher, the ALJ dismissed the complaint. In an initial decision issued on June 27, 2002, the ALJ ruled that Schering's payments to Upsher were solely for licenses to Upsher's products and not in exchange for agreement to the 2001 entry date. The ALJ also held that complaint counsel could not prevail absent proof that the Upsher and AHP products did not infringe Schering's patent. In addition, he found that the relevant product market was all oral potassium supplements, and that Schering did not have monopoly power in that market. Complaint counsel appealed.

On December 8, 2003, the Commission reversed the ALJ's decision. It ruled that Schering paid Upsher to delay the entry of generic competition, and not merely for the products licensed. The Commission also ruled that Schering's agreements with both Upsher and AHP were anticompetitive because Schering's payments resulted in greater protection from competition than the parties expected from continued litigation. In addition, the Commission considered it not necessary or desirable to adjudicate the merits of the underlying patent disputes in order to assess the competitive effects of the agreements.

On March 8, 2005, the Eleventh Circuit set aside the Commission decision, and vacated the cease and desist order. The Eleventh Circuit held the Commission did not establish that the challenged agreements restricted competition beyond the exclusionary effects of Schering's patent. On May 31, 2005, the Eleventh Circuit denied the Commission's petition for rehearing *en banc*. The Commission filed a petition for certiorari in August, 2005. The Supreme Court denied the petition on June 26, 2006.

American Home Products, 133 F.T.C. 611 (2002) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume133.pdf) (see Schering Plough Corporation discussed above). The complaint alleged that Schering agreed to pay ESI Lederle, Inc., a division of American Home Products, to forgo marketing its generic version of K-Dur 20, in connection with settlement of patent infringement litigation. (see Schering Plough Corporation discussed above) ESI agreed, in exchange for the payments, not to market any generic version of K-Dur 20 until January 2004, and to market only one generic version between January 2004 and September 2006 (when Schering's patent expired). ESI also agreed not to prepare, or help any other firm prepare, bioequivalence studies necessary for FDA approval of an application for a generic version of K-Dur 20 until September 2006. American Home Products agreed to a proposed consent agreement and on April 2, 2002, the Commission approved a final order settling the charges against American Home Products. The order prohibits American Home Products, whether acting as a brand or generic competitor, from entering into agreements in which a generic company agrees not to market its drug or enter the market with a non-infringing generic drug.

Hoechst Marion Roussel, Inc./Carderm Capital L.P./Andrx Corp., 131 F.T.C. 927 (2001) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume131.pdf). The complaint alleged that Hoechst and Andrx entered into an agreement in which Andrx was paid millions of dollars to delay bringing to market a competitive generic alternative to Cardizem CD. Andrx, a generic drug manufacturer, was the first to file for FDA approval to market its generic version of Hoechst's brand name hypertension and angina drug, Cardizem CD, but was sued by Hoechst for patent infringement. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180 day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic drug could obtain FDA approval and enter the market during the term of the agreement. Under the agreement, according to the complaint, Andrx agreed not to market its product when it received FDA approval, not to give up or relinquish its 180-day exclusivity right, and not to market a non-infringing generic version of Cardizem CD during the ongoing patent litigation. The order prohibits respondents from

entering into agreements in which the first generic company to file an ANDA agrees: 1) not to relinquish its rights to the 180-day exclusivity period; and 2) not to develop or market a non-infringing generic drug product. The order also requires Hoechst and Andrx to notify the Commission, and obtain court approval, before entering into any agreements involving payments to a generic company in which the generic company temporarily refrains from bringing a generic drug to market.

Abbott Laboratories and Geneva Pharmaceuticals, Inc. C-3945, C-3946 (consent orders issued May 22, 2000) (http://www.ftc.gov/enforcement/cases-proceedings/9810395/abbott-laboratories-matter). The complaint alleged that Abbott paid Geneva $4.5 million per month to delay bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin. Geneva, a generic drug manufacturer, sought and received FDA approval to market its generic capsule version. After Geneva received FDA approval, Abbott and Geneva reached an agreement whereby Geneva would not bring a generic version of Hytrin to market during the ongoing patent litigation on Geneva's tablet version of Hytrin in exchange for the $4.5 million monthly payment, an amount which exceeded the amount Abbott estimated Geneva would have received if it actually marketed the generic drug. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180-day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic Hytrin could obtain FDA approval and enter the market during the term of the agreement. The consent orders prohibit Abbott and Geneva from entering into agreements in which a generic company agrees with the brand drug manufacturer to 1) give up or transfer its Hatch-Waxman 180-day exclusivity rights, or 2) not enter the market with a non-infringing product. In addition, the orders require that agreements involving payments to a generic company to stay off the market during the pendency of patent litigation be approved by the court with notice to the Commission. Geneva was also required to waive its right to a 180-day exclusivity period for its generic tablet, so other generic tablets could immediately enter the market. In a statement accompanying the consent orders, the Commission warned that in the future it will consider its entire range of remedies in enforcement actions against similar arrangements, including seeking disgorgement of illegally obtained profits.

C. Agreements on Price or Price-Related Terms

Cooperativa de Farmacias Puertorriqueñas (Coopharma), FTC. File No. 101 0079 (final consent order issued November 7, 2012) (http://www.ftc.gov/os/caselist/1010079/index.shtm). The complaint alleges that Cooperativa de Farmacias Puertorriqueñas (Coopharma), a Puerto Rico cooperative of approximately 300 pharmacy-owners, has violated federal antitrust laws by negotiating, entering into, and implementing agreements among its member pharmacies to fix prices in their contracts with insurers and pharmacy benefit managers.

Coopharma members own more than 350 pharmacies in Puerto Rico. Its members represent at least one-third of all of the pharmacies in Puerto Rico, and they have a significant presence on the western side of the island.

According to the complaint, since at least 2007 Coopharma has negotiated with more than 10 payers over reimbursement rates and signed "single-signature" master contracts on behalf of its member pharmacies. In addition, the threat of collective action by Coopharma members led two payers to pay higher rates to the group's members through their individual pharmacy contracts.

The order prohibits Coopharma from entering into or facilitating agreements between or among any pharmacies to, among other things, negotiate on behalf of any pharmacy with any payer and refuse to deal with any payer. The order also prohibits Coopharma from facilitating information exchanges between pharmacies regarding whether to contract with a payer and inducing anyone to engage in the prohibited conduct.

Under the order, payers are allowed to terminate their contracts with Coopharma without penalty, and Coopharma must notify each pharmacy providing services under the contract of the termination.

Asociacion de Farmacias Region de Arecibo, 127 F.T.C. 266 (1999) (consent order) (*not currently available online at FTC.gov*). The complaint alleged that an association, composed of approximately 125 pharmacies in northern Puerto Rico, fixed the terms and conditions, including fixing prices, of dealing with third party payers, and threatened 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 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.

Institutional Pharmacy Network, 126 F.T.C. 138 (1998) (consent order) (http://www.ftc.gov/os/decisions/docs/vol126/FTC_VOLUME_DECISION_126_(JULY_-_DECEMBER_1998)PAGES_105-201.pdf#page=34). 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) competed 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.

RxCare of Tennessee, Inc. et al., 121 F.T.C. 762 (1996) (consent order) (http://www.ftc.gov/os/decisions/docs/vol121/FTC_VOLUME_DECISION_121_(JANUARY_-_JUNE_1996)PAGES_762-860.pdf). The complaint charged 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 included 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. The order bars RxCare from including the MFN clause in its pharmacy agreements.

Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists Association, 117 F.T.C. 95 (1994) (consent order) (http://www.ftc.gov/os/decisions/docs/vol117/FTC_VOLUME_DECISION_117_(JANUARY_-_JUNE_1994)PAGES_1_-103.pdf#page=95). 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.

Southeast Colorado Pharmacal Association, 116 F.T.C. 51 (1993) (consent order) (http://www.ftc.gov/os/decisions/docs/vol116/FTC_VOLUME_DECISION_116_(JANUARY_-_DECEMBER_1993)PAGES_1-112.pdf#page=49). 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.

Peterson Drug Company, 115 F.T.C. 492 (1992) (litigated order) (http://www.ftc.gov/os/decisions/docs/vol115/FTC_VOLUME_DECISION_115_(JANUARY_-_DECEMBER_1992)PAGES_433-559.pdf#page=60). As a member firm of Chain Pharmacy Association, Peterson Drug Company was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan, an attempt by New York State to reduce the reimbursement received by pharmacies participating in the state's employee prescription drug plan. After Peterson failed to appeal an Administrative Law Judge's decision in favor of complaint counsel, the Commission adopted the initial decision and entered an order similar to the Chain Pharmacy order (discussed below).

Chain Pharmacy Association, 114 F.T.C. 327 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991_)PAGES_250-366.pdf#page=78). The complaint charged 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 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 third-party payer prescription drug plans. Also, for a period of ten years, the order prohibits Chain from communicating to any pharmacist or pharmacy firm 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 below).

Fay's Drug Company, Inc., 114 F.T.C. 344 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991_)PAGES_250-366.pdf#page=95). As a member firm of Chain Pharmacy Association, Fay's Drug Company, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan, an attempt by New York State to reduce the reimbursement received by pharmacies participating in the state's employee prescription drug plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Kinney Drugs, Inc., 114 F.T.C. 367 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_

-_DECEMBER_1991)PAGES_367-485.pdf). As a member firm of Chain Pharmacy Association, Kinney Drugs, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan, an attempt by New York State to reduce the reimbursement received by pharmacies participating in the state's employee prescription drug plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Melville Corporation, 114 F.T.C. 171 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991)PAGES_152-249.pdf#page=20). As a member firm of Chain Pharmacy Association, Melville Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan, an attempt by New York State to reduce the reimbursement received by pharmacies participating in the state's employee prescription drug plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Rite Aid Corporation, 114 F.T.C. 182 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991)PAGES_152-249.pdf#page=31). As a member firm of Chain Pharmacy Association, Rite Aid Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan, an attempt by New York State to reduce the reimbursement received by pharmacies participating in the state's employee prescription drug plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

James E. Krahulec, 114 F.T.C. 372 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991)PAGES_367-485.pdf#page=6). As a member firm of Chain Pharmacy Association, James E. Krahulec, along with Rite Aid and the members of Chain Pharmacy Association, was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Pharmaceutical Society of the State of New York, Inc., 113 F.T.C. 661 (1990) (consent order) (http://www.ftc.gov/os/decisions/docs/vol113/Volume113_625-714.pdf#page=37). The complaint charged 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 order, 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 requires PSSNY to refrain 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. For a period of eight years, the order prohibits PSSNY from providing comments or advice to any pharmacist or pharmacy on the desirability of participating in any existing or proposed participation agreement. *See* Chain Pharmacy Association (discussed above).

Empire State Pharmaceutical Society, Inc., 114 F.T.C. 152 (1991) (consent order) (http://www.ftc.gov/os/decisions/docs/vol114/FTC_VOLUME_DECISION_114_(_JANUARY_-_DECEMBER_1991)PAGES_152-249.pdf). An affiliate of Long Island Pharmaceutical Society, Empire State Pharmaceutical Society 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.

Capital Area Pharmaceutical Society, 114 F.T.C. 159 (1991) (consent order) (http://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114). An affiliate of PSSNY, Capital Area Pharmaceutical Society 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.

Alan Kadish, 114 F.T.C. 167 (1991) (consent order) (http://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114). 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.

Long Island Pharmaceutical Society, Inc., 113 F.T.C. 669 (1990) (consent order) (http://www.ftc.gov/os/decisions/docs/vol113/Volume113_625-714.pdf#page=45). An affiliate of PSSNY, Long Island Pharmaceutical Society, Inc. 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.

Pharmaceutical Society of Orange County, Inc., 113 F.T.C. 645 (1990) (consent order) (http://www.ftc.gov/os/decisions/docs/vol113/Volume113_625-714.pdf#page=21). An affiliate of PSSNY, Pharmaceutical Society of Orange County, Inc. 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.

Westchester County Pharmaceutical Society, 113 F.T.C. 159 (1990) (consent order) (http://www.ftc.gov/os/decisions/docs/vol113/Volume113_625-714.pdf#page=29). An affiliate of PSSNY, Westchester County Pharmaceutical Society, Inc. 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.

Brooks Drug, Inc., 112 F.T.C. 28 (1989) (consent order) (http://www.ftc.gov/os/decisions/docs/vol112/FTC_VOLUME_DECISION_112_(_JULY_-_DECEMBER_1989)PAGES_1-174.pdf#page=28). As a member firm of Chain Pharmacy

Association, Brooks Drug Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Carl's Drug Co., Inc., 112 F.T.C. 15 (1989) (consent order) (http://www.ftc.gov/os/decisions/docs/vol112/FTC_VOLUME_DECISION_112_(_JULY_-_DECEMBER_1989)PAGES_1-174.pdf#page=15). As a member firm of Chain Pharmacy Association, Carl's Drug Co., Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

Genovese Drug Stores, Inc., 112 F.T.C. 23 (1989) (consent order) (http://www.ftc.gov/os/decisions/docs/vol112/FTC_VOLUME_DECISION_112_(_JULY_-_DECEMBER_1989)PAGES_1-174.pdf#page=23). As a member firm of Chain Pharmacy Association, Genovese Drug Stores, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

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

Inverness Medical Innovations, Inc. (See Section II A for citation and annotation.)

Asociacion de Farmacias Region de Arecibo (See Section II C for citation and annotation.)

E. Illegal Tying and Other Arrangements

CVS Caremark Corporation, FTC File No. 112-3210 (consent order issued January 12, 2012) (http://www.ftc.gov/os/caselist/1123210/index.shtm). The complaint charges that CVS Caremark misrepresented the prices of certain Medicare Part D prescription drugs – including drugs to treat epilepsy and symptoms of breast cancer– at CVS and Walgreen pharmacies. The allegedly deceptive claims caused many seniors and disabled consumers to pay significantly more for their drugs than they expected. These increased prices pushed them into the "donut hole" – a term referring to the coverage gap where drug costs are not reimbursed – sooner than they had anticipated.

According to the complaint, CVS Caremark offers Medicare Part D prescription drug plans through subsidiaries like RxAmerica, which CVS Caremark acquired in October 2008. Many consumers choose their Medicare Part D drug plans by (1) looking up plan benefits and drug prices on RxAmerica's website, (2) going to the Centers for Medicare & Medicaid Services website and using the web-based tool Plan Finder, or (3) visiting other third-party websites where such information is posted. The FTC charged that from 2007 through at least November 2008, RxAmerica posted on its website and supplied for posting to Plan Finder and third-party websites incorrect prices for Medicare Part D prescription drugs at two pharmacy chains, CVS and Walgreens. In some instances the actual prices for these drugs were as much as 10 times

more than the posted prices. As a consequence of the deceptive price claims, many elderly and disabled consumers chose RxAmerica plans and paid significantly more than they expected for their drugs at CVS and Walgreens.

The proposed settlement order prohibits CVS Caremark from misrepresenting the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans. It requires CVS Caremark to pay $5 million in consumer refunds. The consent agreement was subject to public comment for 30 days, until February 13, 2012, after which the Commission will decide whether to make the proposed consent order final. The Commission will mail check to eligible consumers who were harmed by the misrepresentations after the order becomes final.

Sandoz Pharmaceuticals Corporation, 115 F.T.C. 625 (1992) (consent order) (http://www.ftc.gov/os/decisions/docs/vol115/FTC_VOLUME_DECISION_115_(JANUARY_-_DECEMBER_1992)PAGES_560-669.pdf#page=66). The complaint charged 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 order prohibits Sandoz from requiring any purchaser of clozapine, or a patient taking clozapine, to buy other goods or services from Sandoz. The order 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.

III. PHARMACEUTICAL MERGERS

A. Horizontal Mergers Between Direct Competitors

Watson Pharmaceuticals Inc., C-4373 (final order issued December 14, 2012) (http://www.ftc.gov/enforcement/cases-proceedings/1210132/watson-pharmaceuticals-actavis-inc) The FTC complaint alleged that the proposed acquisition by Watson Pharmaceuticals, Inc. of Actavis Inc. would violate federal antitrust laws by reducing competition in 21 generic drug markets. Watson is a global pharmaceutical company based in Parsippany, New Jersey that specializes in the development, production, and marketing of generic and branded drugs as well as active pharmaceutical ingredients (APIs). It is the fourth largest generic company in the world, with production facilities in North and South America, Europe, and Asia. In the United States, Watson markets more than 160 generic pharmaceutical product families. Actavis,

headquartered in Switzerland, is also a global pharmaceutical company engaged in the development, production, and marketing of generic drugs, APIs and over-the-counter drugs. Its production facilities are in Europe, Asia and the United States. Actavis is the ninth-largest generic drug company in the United States. It markets more than 1100 pharmaceutical products. Of the 21 generic drug markets in which the proposed acquisition was likely to reduce competition, seven of the markets involved generic drugs that are currently sold, eight markets involve generic drug products that either one or both of the companies currently sell or have in development, and both companies have generic products in development in the remaining relevant markets. These 21 generic markets are or are expected to be concentrated, and Watson and Actavis are currently one or expected to be one of only a few competitors.

Currently Marketed Products. The complaint alleges that the proposed acquisition would reduce competition in markets for the following seven drugs: (1) the generic version of GlaxoSmithKline plc's extended-release Zyban, designed to help people to quit smoking; (2) the generic version of extended-release Cardizem CD, used to treat hypertension, angina, and certain heart rhythm disorders, (3) the generic version of Janssen Pharmaceuticals, Inc.'s fentanyl patch system, used to ease chronic pain; (4) the generic version of Valeant Pharmaceuticals International's Ativan, used to treat anxiety disorders; (5) the generic version of Anio Pharmaceuticals, Inc.'s Reglan, used to treat nausea; (6) the generic version of Actavis' extended-release drug Kadian, used to treat acute pain; and (7) the generic version of Bayer AG's extended-release drug Adalat CC, used to treat hypertension and angina.

Generic Products in the Pipeline. The complaint also alleges that the proposed acquisition would reduce competition significantly in the future for the following eight drugs: (1) the generic version of extended-release Adderall XR, used to treat ADHD; (2) the generic version of extended-release Tiazac capsules, used to treat hypertension and angina; (3) the generic version of Endo Health Solutions, Inc.'s extended-release Opana ER tablets, used to treat chronic pain; (4) an alternate generic version of Watson and Pfizer, Inc.'s extended-release glipizide diabetes medication; (5) an alternate generic version of Dynacirc, used to treat high blood pressure; (6) an alternate generic version of Loxitine, used to treat the symptoms of schizophrenia; (7) the generic version of Janssen's extended-release Concerta, used to treat ADHD in people over age six; and (8) alternate generic versions of Watson's Urso 250 and Urso Forte, which are used to treat a certain type of cirrhosis.

Future Products in Development. Finally, the complaint alleges that the proposed acquisition would reduce future competition in the markets for the following six genetic drugs that are not on the market but are currently in development by Watson and Actavis: (1) a topical treatment for acne; (2) a product to treat the symptoms of certain neurological diseases; (3) a product used to treat acne pain; (4) a generic version of the tamper-resistant pain relief drug OxyContin; (5) an extended-release patch used to treat Alzheimer's disease and dementia resulting from Parkinson's disease; and (6) a generic version of Pfizer's Chantix, used to help people stop smoking.

The order requires the companies to sell either Watson's or Actavis' rights and assets to 18 of the 21 drugs to an FTC-approved buyer within 10 days of the acquisition. It requires the sale of

four of the 18 drugs to Sandoz and the remaining 14 drugs to Par. To remedy the Commission's concerns relating to one of the three remaining drug products, the combined firm is required to end Actavis' existing development and manufacturing agreement with Pfizer and transfer the manufacturing rights back to Pfizer. For the other two drugs, Watson and Actavis must relinquish the marketing rights to another firm.

If the FTC determines that Par and/or Sandoz are not acceptable buyers for the 18 drugs, the order requires Watson and Actavis to abandon the deals and find new Commission-approved buyers within six months of the time the deal becomes final. Watson and Actavis must also maintain the viability of the drugs until they are transferred to an FTC-approved buyer to ensure that the divestitures are successful.

Novartis, AG, FTC File No. 210144, Docket No. C-4364 (final order issued September 5, 2012) (http://www.ftc.gov/enforcement/cases-proceedings/121-0144/novartis-ag-matter) In its complaint the Commission charges that Novartis' proposed acquisition of Fougera Holdings, Inc. would harm competition in the market for four topical skin care medications. According to the complaint, the acquisition if consummated would violate Section 5 of the FTC Act and Section 7 of the Clayton act by reducing competition in the generic drug market for (1) generic calcipotriene topical solution, (2) generic lidocaine-prilocaine cream, and (3) generic metronidazole topical gel. The complaint also alleges that the acquisition would eliminate potential competition in the market for diclofenac sodium gel.

Generic calcipotriene topical solution is used for the treatment of chronic, severe scalp psoriasis. The three firms that offer a generic version of the drug in the United States are Novartis, Fougera and G&W Laboratories. Novartis has the leading market share of 67 percent, followed by G&W with 22 percent and Fougera with 11 percent.

Generic lidocaine-prilocaine cream is used as an anesthetic to prevent pain resulting from injections and surgery. The cream is available in 30 gram tubes and packages of five 5 gram tubes, known as 5-5 tubes. The 30 gram tubes are prescribed for home use and the 5-5 tubes are only used in hospitals. Fougera, Hi-Tech Pharmaceutical Co. and Novartis are the only U.S. firms that supply 30 gram tubes. Novartis and Fougera are the only two U.S. suppliers of the 5-5 tubes. The proposed acquisition would create a duopoly in the U.S. market for 30 gram tubes and a monopoly in the U.S. market for general 5-5 tubes.

In each of these three markets, the proposed acquisition is likely to facilitate price increases, or eliminate price decreases, by eliminating one of a limited number of suppliers.

Fougera markets a branded drug Solaraze, which is used to treat actinic keratosis. The drug is a formulation containing the active ingredient diclofenac sodium. Novartis is best-positioned to become the first generic competitor for the drug. If consummated, the proposed acquisition is likely to reduce the number of competitors for diclofenac sodium gel in the future.

Tolmar, Inc. is the Colorado-based developer and manufacturer of each of the four generic drugs. Under the settlement order, Novartis is required to end its marketing agreement with Tolmar

with respect to generic calcipotriene topical solution, generic lidocaine-prilocaine cream and generic metronidazole topical gel, and return to Tolmar all rights to distribute, market and sell these products. It is also required to end its marketing agreement with Tolmar and return to Tolmar all rights to develop, distribute, market and sell the development product generic diclofenac sodium gel. If Novartis fails to comply fully with its obligations to return to Tolmar all rights to the drugs, the order allows the FTC to appoint a trustee to ensure that the assets are returned as required. The FTC also has appointed an interim monitor to ensure that Novartis complies expeditiously with the order's requirements.

Valeant Pharmaceuticals International Inc., Docket No. 4342, FTC. File No. 111-0215 (complaint and proposed order issued December 9, 2011; final order approved February 22, 2012) (http://www.ftc.gov/os/caselist/1110215/index.shtm). The complaint alleges that Valeant's proposed acquisition of Dermik Laboratories, Inc. from Sanofi would illegally reduce competition in the U.S. market for two topical skin-care drugs: (1) BenzaClin and its generic equivalent – a combination of an antibiotic and an antimicrobial – that are used to treat common acne, and (2) topical fluorouracil cream, or topical 5FU, which is used to treat actinic keratosis, a pre-cancerous lesion resulting from years of extensive sun exposure.

Dermik, Sanofi's dermatological unit, manufactures and markets BenzaClin. Valeant owns the only Abbreviated New Drug Application for the generic version of BenzaClin, which it licenses to Mylan, Inc. Under the licensing agreement, Mylan sells the generic version of BenazClin and Valeant receives royalties from those sales. Currently in the BenzaClin market, Dermik's sales account for approximately 50 percent of unit sales, and unit sales of Mylan's generic version account for the other approximate 50 percent. The proposed acquisition would create a monopoly in this market. There are three branded topical 5FUs currently on the market: Valeant's Efudex, Dermik's Carac and Allergan, Inc.'s Fluoroplex. Two generic companies, Spear Pharmaceuticals and Taro Pharmaceuticals U.S.A., market generic versions of Efudex, and Valeant also markets an authorized generic of the drug. Sales of Efudex have almost completely been replaced by sales of the three generic equivalents of the drug, and Dermik's Carac is priced directly against the three generic versions of Efudex. After the acquisition Valeant's share in the topical 5FU market would be over 50 percent. The complaint alleges that these acquisitions would lead to higher prices for consumers.
The order required Valeant to sell to Mylan all rights to generic BenzaClin. It also required Valeant to license to Mylan the rights to manufacture and market the authorized general version of Efudex.

Valeant Pharmaceuticals International Inc., Docket No. 4343, FTC. File No. 111-0216 (complaint and proposed order issued December 9, 2011; final order approved February 22, 2012) (http://www.ftc.gov/os/caselist/1110215/index.shtm). The FTC's complaint charges that Valeant's proposed acquisition of Ortho Dermathologics, a division of Johnson & Johnson's Janssen Pharmaceuticals, Inc. would cause significant harm to consumers of prescription tertinoin emollient creams, which are topical products derived from Vitamin A and used to treat fine line wrinkles. Valeant markets branded Refissa tretinoin emollient cream and a generic emollient cream pursuant to a license agreement with Spear Pharmaceuticals. Johnson & Johnson's branded Renova is the only other tretinoin emollient cream product on the market.

Post-acquisition Valeant would have a monopoly in the U.S. market for tertinoin emollient cream, and higher prices for consumers would likely occur, according to the complaint.

The order required Valeant to return all marketing rights to Refissa and the generic tertinoin emollient cream to Spear Pharmaceuticals.

Teva Pharmaceutical Industries Ltd., FTC File No. 111 0166 (amended final order issued July 3, 2012) (http://www.ftc.gov/os/caselist/1110166/index.shtm) The Commission alleges in its complaint that the proposed acquisition by Teva Pharmaceutical Industries Ltd. (Teva) of Cephalon, Inc. (Cephalon) would reduce competition and lead to higher prices in the following three markets:

(1) *transmucosal fentanyl citrate lozenges,* which are versions of the cancer pain drug developed by Cephalon and marketed under the brand name Actiq. Three generic versions of the drug are manufactured and marketed in the U.S. by Teva, Cephalon/Watson Pharmaceuticals and Covidien. After Teva's acquisition of Cephalon, the number of manufacturers of the drug would be reduced to two, and Teva would have more than an 80 percent share of the sales of the generic Actiq product;

(2) *extended release cyclobenzaprine hydrochloride,* an extended release version of the muscle relaxant Flexeril. Cephalon acquired the rights to Amrix, the branded version of the drug, which was approved by the FDA in 2007. No companies currently make or market a generic version of Amrix; however, Teva and Cephaon are two of only a limited number of suppliers that may be able to enter the market quickly with a generic product; and

(3) *modafinil tablets,* versions of the brand name drug Provigil, which is marketed by Cephalon and used to treat excessive sleepiness due to narcolepsy or shift work disorder. At the time of the proposed acquisition no company marketed a generic version of Provigil. Teva, Ranbaxy Pharmaceuticals, Inc., Mylan Pharmaceutical Inc., and Barr Laboratories, Inc. (which Teva now owns), had all taken steps toward entering the market, and all were eligible to seek a 180-day marketing exclusivity period as provided under federal law. However, each company had signed an agreement with Cephalon to refrain from marketing generic Provigil until April 2012. The acquisition as proposed would make Teva and Cephalon two of only a limited number of suppliers of generic Provigil during the 180-day exclusivity period.

In a settlement order, the Commission required Teva to sell the rights and assets relating to generic Actiq or transmucosal fentanyl citrate lozenges, and Actiq or generic extended release cyclobenzaprine hydrochloride capsules, to Par Pharmaceuticals, Inc. (Par), a generic drug manufacturer based in New Jersey. The divestiture was required to be completed within 10 days of the acquisition.

In its amended final order issued July 3, 2012, the Commission modified the proposed order to account for changed circumstances related to the transaction's effect on generic competition of Provigil. In order to remedy the consolidation of marketers of generic Provigil during the 180-day exclusivity period, the order initially required Teva to enter into a supply agreement to

provide Par with generic Provigil tablets in the United States in 2012. This agreement allowed Par to compete with a generic Provigil product during the 180-day exclusivity period. Par could also extend the supply agreement for another year.

The provisions in the order concerning generic Provigil were based on evidence that Mylan, Ranbaxy and Barr were positioned to launch generic versions of Provigil on April 6, 2012. However, these firms did not enter into the generic Provigil market as expected, and Teva was awarded sole 180-day generic marketing exclusivity for generic Provigil. As of July 3, 2012 the only firms that have launched generic Provigil are Teva and Par, which is supplied by Teva under the proposed order.

To assure that the FDA will be able to approve additional companies seeking to market generic Provigil when the 180-day exclusivity period expires in September 2012, the final consent order provides that Teva will not challenge the FDA's determination that the 180-day exclusivity period for generic Provigil began to run on March 30, 2012. Also, Teva addressed the concern of the absence of an independent generic competitor by entering into a license agreement with Mylan that provides for Mylan's entry as of August 10, 2012, 45 days early.

Perrigo Company, C-4329, FTC File No. 111-0083 (final consent order issued June 26, 2012) (http://www.ftc.gov/os/caselist/1110083/index.shtm) The complaint charged that the $540 million acquisition of Paddock Laboratories, Inc. (Paddock) by Perrigo Company would reduce the number of suppliers for four generic drugs and harm future competition in the market for three generic drugs. The six markets are described below:
(1) *Ammonium lactate cream and ammonium lactate lotion* are prescription moisturizers used to treat dry, scaly skin conditions and to help relieve itching. After the acquisition the combined Perrigo/Paddock would control 87 percent of the ammonium lactate cream market and 93 percent of the ammonium lactate lotion market.
(2) *Ciclopirox* is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. The combined firm, after the acquisition, would control 99 percent of this market.
(3) *Promethazine suppositories* are used to treat allergic reactions, prevent and control motion sickness, and relieve nausea and vomiting associated with surgery. Perrigo, Paddock and G&W Laboratories, Inc. are the only U.S. suppliers of the 12.5 mg and 25 mg strengths of this product. As a result of the acquisition, the combined firm would have 34 percent of the market for the 12.5 mg strength and 35 percent of the market for the 25 mg strength.
(4) *Generic clobestasol spray* is a topical steroid used to treat moderate psoriasis in adults. Perrigo and Paddock are developing clobestasol sprays and are two of a limited number of suppliers capable of entering this future market in a timely manner. The complaint alleges that the acquisition would eliminate important future competition for product and result in higher prices for U.S. consumers.
(5) *Generic diclofenac solution* is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are in the process of entering the diclofenac solution market and are among a limited number of suppliers that can enter this future market in a timely manner. According to the complaint, the acquisition would result in the elimination of future competition for this product, followed by higher prices to consumers in the U.S.

(6) *Testosterone gel* is used to treat adult males who have a deficiency or absence of testosterone. Abbott Laboratories (Abbott) markets testosterone gel under the brand name AndroGel. Perrigo is among a limited number of suppliers capable of entering this future market in a timely manner. Paddock will receive substantial payments from Abbott pursuant to an agreement that Par Pharmaceutical Companies, Inc. has with Abbott that relates to AndroGel. The complaint alleges that the acquisition will increase the likelihood of coordinated interaction between Abbott and Perrigo in the market for testosterone gel; increase the likelihood that the combined firm would forego or delay the launch of Perrigo's product in the market; and increase the likelihood that the combined firm would delay or eliminate the competition that Perrigo's independent entry into the testosterone gel market would have created.

The settlement order requires the combined Perrigo-Paddock to sell all Perrigo or Paddock assets related to the six products to Watson Pharmaceuticals, Inc. within 10 days of the acquisition. The order also requires the combined firm to provide Watson with the transitional services it needs to manufacture and sell the divested products successfully.

To preserve competition in the testosterone gel market, the order prohibits Perrigo from accepting payments from Abbott relating to AndroGel. It also bars Perrigo from entering into any "pay-for-delay" arrangements with Abbott. ("Pay-for-delay" arrangements occur when a branded drug firm pays its generic competitor to settle pending patent litigation and delay generic entry. The Commission deems these arrangements to be anticompetitive.)

Cardinal Health, Inc./Biotech Pharmacy Inc., *et.al.*, FTC File No. 091-0136 (complaint issued July 21, 2011; final order issued October 21, 2011) (http://www.ftc.gov/os/caselist/0910136/index.shtm) The complaint charges that the purchase by Cardinal Health, Inc. (Cardinal) of nuclear pharmacies from Biotech Pharmacy Inc., *et al.* (Biotech) reduced competition for low-energy radiopharmaceuticals in three cities. The Commission has approved an order requiring Cardinal to reconstitute and sell certain nuclear pharmacies to restore competition lost as a result of the acquisition.

Nuclear pharmacies provide radiopharmaceuticals to hospitals and cardiology clinics, which use the products to diagnose and treat various diseases. Radiopharmaceuticals contain a radioisotope that is combined with a chemical compound. Because radioisotopes used in radiopharmaceuticals have short half-lives and decay rapidly, competition among nuclear pharmacies occurs locally. On July 31, 2009 Cardinal acquired certain assets of Biotech, including its nuclear pharmacies in Las Vegas, Albuquerque, and El Paso. Prior to the acquisition, Cardinal and Biotech both operated nuclear pharmacies in these three cities. The pharmacies produced, sold and distributed low-energy radiopharmaceuticals. After the acquisition Cardinal relocated the nuclear pharmacy business to the former Biotech nuclear pharmacy locations and closed its own locations. Cardinal now holds a low-energy radiopharmaceuticals monopoly in Albuquerque. In El Paso, although another nuclear pharmacy opened November, 2010, Cardinal still holds a large market share. In Las Vegas, there were three competitors before the acquisition; Cardinal and Biotech were the leading providers. As a result of the acquisition, Cardinal obtained, and has since held, a large market share. Cardinal's acquisition of Biotech's nuclear pharmacies may substantially lessen competition for the

production, sale and distribution of low-energy pharmaceuticals in the three cities by eliminating direct competition between Cardinal and Biotech and allowing Cardinal to increase prices and reducing Cardinal's incentive to improve customer service.

The order required Cardinal to reconstitute the three nuclear pharmacies it had operated in Las Vegas, Albuquerque and El Paso before the acquisition and sell each one to an FTC-approved buyer. The terms of the order also required Cardinal to grant its customers in Las Vegas, Albuquerque and El Paso a two-year right to terminate, without penalty or charge, their existing contracts with Cardinal to buy low-energy radiopharmaceuticals.

Grifols. S.A., C 4322, FTC File No. 101-0153 (complaint issued May 31, 2011; final order issued July 20, 2011) (http://www.ftc.gov/os/caselist/1010153/index.shtm)
The complaint charged that the proposed acquisition by Grifols, S.A. (Grifols) of Talecris Biotherapeutics Holdings Corp.(Talecris) would be anticompetitive because it would eliminate direct competition for products in three blood plasma-derived markets. The Commission approved a final order on July 20, 2011 requiring Grifols to make significant divestitures prior to its acquisition of Talecris. Grifols, headquartered in Barcelona, Spain develops and manufactures human blood plasma-derived products and has facilities in Barcelona and Los Angeles. Talecris is based in Research Triangle Park, North Carolina and also develops, manufactures and sells blood plasma-derived products worldwide. The FTC complaint alleged that Grifols' proposed acquisition of Talecris would lessen competition in the U.S. markets for three blood plasma-derived products: (1) Immune globulin (Ig), which is used to treat, among other things, immune deficiencies and neurological disorders; (2) albumin, which is used to expand blood volume, prime heart valves during cardiac surgery, treat burn victims, and replace proteins in patients suffering from liver failure; and (3) plasma-derived Factor VIII (pdFVIII), which is used to treat bleeding disorders, primarily hemophilia and von Willebrand disease. Each of these products must be approved by the Food and Drug Administration for sale in the United States. The FDA requires that the products be made only from plasma collected in the United States and manufactured at FDA-approved plants.

Grifols and Talecris currently have approximately 8.4 percent and 22.8 percent of the U.S. Ig market, respectively. Their merger would leave only three significant manufacturers with nearly all of the U.S. Ig sales. In the market for albumin, the companies have shares in the U.S. of approximately 13 percent each, and the acquisition would leave only four significant competitors. Grifols and Talecris have 23 percent and 3.6 percent of the U.S. pdFVIII market, and after the merger there would be only three main competitors. According to the FTC, with fewer competitors in the market, the remaining firms could more easily work together through coordinated interaction to reduce supply and raise price for consumers. The FTC's order requires Grifols to (1) sell the fractionation facility Talecris currently owns in Melville, New York to Kedrion, S.p.A. (Kedrion), a manufacturer of plasma-derived products in Europe and other markets and a new entrant in the U.S. plasma-derived products industry; (2) sell to Kedrion its plasma collection centers in Mobile, Alabama, and Winston-Salem, North Carolina; (3) sell Talecris' Koate pdFVIII business, including the Koate brand name in the United States, to Kedrion; and (4) manufacture private-label Ig, private label albumin, and Koate for seven years for Kedrion to sell in the United States. The order is designed to expedite Kedrion's entry as an

additional competitor into each of the three blood plasma-derived markets by ensuring that Kedrion will have adequate supplies of Ig, albumin and pdFVIII to sell in the United States. The order will make a potential industry-wide coordinated plan to raise prices more difficult and limit Grifols' ability to raise prices post-merger.

Hikma Pharmaceuticals PLC, C. 4320, FTC File No.111-0051 (complaint issued April 25, 2011; final order issued June 6, 2011) (http://www.ftc.gov/os/caselist/1110051/index.shtm) The complaint alleged that the acquisition by Hikma Pharmaceuticals PLC (Hikma) of the generic injectable phenytoin and promethazine businesses of Baxter Healthcare Corporation, Inc. (Baxter) would be anticompetitive and likely would result in higher prices for both drugs. As part of a settlement that would allow Hikma to acquire certain assets from Baxter, the Commission will require Hikma to divest those two injectable pharmaceutical businesses. Hikma proposes to acquire for $111.5 million Baxter's entire generic injectable pharmaceutical business, including a manufacturing facility in Cherry Hill, New Jersey and a warehouse and distribution center in Memphis, Tennessee.

Phenytoin is an anti-convulsant drug used to control and prevent seizures during or after surgery. Promethazine is used to prevent some types of allergies or allergic reactions, to prevent or control motion sickness, nausea, vomiting and dizziness, and to help patients go to sleep and control their pain or anxiety before or after surgery. As originally proposed, Hikma's acquisition would eliminate competition between Hikma and Baxter and likely result in harm to consumers by increasing prices for both products. The complaint alleges that the U.S. markets for both products are already highly concentrated; Hikma, Baxter and Hospira, Inc. are the only companies that currently compete to provide phenytoin and promethazine.

The settlement order requires Hikma, within 10 days of the acquisition, to divest certain rights and assets related to generic injectable phenytoin and promethazine to X-Gen Pharmaceuticals Inc. (X-Gen), which is based in New York. According to the Commission, X-Gen is a pharmaceutical firm with 40 products and an active product development pipeline; thus it will be able to replace the competition that the acquisition would have eliminated, and customers for the two drugs will be better protected against potential price increases.

Novartis AG (See Section II A for citation and annotation.)

Schering-Plough Corporation/Merck & Co., Inc. (See Section II A for citation and annotation.)

Pfizer, Inc./Wyeth (See Section II A for citation and annotation.)

CSL Limited/Cerberus-Plasma Holdings, LLC (See Section II A for citation and annotation.)

Teva Pharmaceutical Industries Ltd./Barr Pharmaceuticals, Inc., C-4242 (consent order issued February 9, 2009) (http://www.ftc.gov/enforcement/cases-proceedings/081-0224/teva-pharmaceutical-industries-ltd-corporation-barr). The complaint alleged that Teva's acquisition of Barr would lessen competition in 29 U.S. generic drug markets, including:

■ *Tetracycline HCl tablets; Chlorzoxazone tablets; Desmopressin acetate tablets.* Tetracycline HCl is an old, broad-spectrum antibiotic used now primarily for the treatment of acne and rosacea. Chlorzoxazone is a centrally acting muscle relaxant used to treat muscle spasms. Desmopressin acetate is a synthetic replacement for an antidiuretic hormone that reduces urine production during sleep, and is used to treat bed-wetting in children. Because Teva and Barr are the only suppliers of these generic products in the U.S., the proposed acquisition would create a monopoly in each of these three markets.

■ *Tamoxifen citrate; Cyclosporine liquid.* Tamoxifen citrate is a selective estrogen receptor modulator that is used in the treatment of breast cancer. Cyclosporine is an immunosuppressant used to prevent the rejection of transplanted organs. Combined, Teva and Barr currently account for 73 percent of the generic tamoxifen citrate market and 55 percent of the generic cyclosporine liquid market. The proposed acquisition would reduce the number of competitors in each market from three to two.

■ *Metoclopramide HCl tablets; Carboplatin injection; Metronidazole tablets; Trazodone HCl tablets; Cyclosporine capsules; Flutamide capsules; Glipizide/metformin HCl tablets; Deferoxamine injection; Mirtazapine ODT.* The proposed acquisition would reduce the number of competitors in the U.S. from four to three in each of these nine markets.

- Metoclopramide HCl is a dopamine receptor antagonist used to treat nausea and vomiting as well as gastroesophageal reflux disease. Teva and Barr are two of only four suppliers supplying all dosage forms of this generic drug. A combined Teva/Barr would possess 82 percent of the overall metoclopramide HCl market.

- Carboplatin is a chemotherapy drug used to treat ovarian, lung, head, neck, and certain other cancers. Teva and Barr are two of the leading suppliers of generic carboplatin injection, with a combined market share of 60 percent.

- Metronidazole is an anti-infective used in the treatment of a variety of bacterial infections. Barr and Teva have 50 percent and 39 percent, respectively, of the generic metronidazole market.

- Trazodone is an antidepressant with a sedative effect. The proposed acquisition would result in a combined Teva/Barr share of 75 percent of the generic trazodone market.

- Cyclosporine is an immunosuppressant used to prevent the rejection of transplanted organs. In the generic cyclosporine tablets market, Teva and Barr have roughly equal shares, and a combined share of 41 percent.

- Flutamide is an anti-androgen drug used to treat prostate cancer. In the generic flutamide market, Teva and Barr have shares of 28 percent and 14 percent, respectively.

- Glipizide/metformin is commonly prescribed as a first line treatment for diabetes. Teva and Barr have 26 percent and 25 percent shares, respectively.

- Deferoxamine is a chelating agent used to remove excess iron from the body. In the generic deferoxamine market, a combined Teva and Barr would possess 16 percent of the market.

- Mirtazapine is an antidepressant used to treat moderate to severe depression. Barr and Teva have 26 percent and 10 percent, respectively, of the generic mirtazapine market.

■ *Epop; Fluoxetine weekly capsules.* In these two product markets, the proposed acquisition would eliminate important and significant future competition. Epop is used to treat severe primary pulmonary hypertension. Epop is a new generic market, and Teva is currently the only generic epop supplier. However, Barr is developing a generic epop product. Fluoxetine weekly capsules are a widely-prescribed antidepressant; and both Teva and Barr have generic products in development for this market. Few other firms are capable of, or interested in, entering these markets.

■ *Oral contraceptives.* Oral contraceptives are pills taken by mouth to prevent ovulation and pregnancy, and are the most common method of reversible birth control. Teva's acquisition of Barr is likely to lessen competition in 13 oral contraceptive markets, including: two markets in which both Teva and Barr participate; ten markets in which Barr participates and Teva is developing a product; and one market in which both Teva and Barr are developing products.

- Teva and Barr both participate in the generic Ortho-Cyclen and generic Ortho Tri-Cyclen markets, both of which are already highly concentrated, with only one other firm participating in each market. A combined Teva and Barr would have 61 percent of the generic Ortho-Cyclen market, and 51 percent of the generic Ortho Tri-Cyclen market.

- Barr competes in ten oral contraceptives markets where Teva is developing a competing product. These markets include generic products equivalent to: Ortho-Cept; Mircette; Triphasil; Alesse; OrthoNovum 1-35; OrthoNovum 7/7/7; Loestrin FE (1 mg/.02 mg & 1.5 mg/.03 mg); Loestrin FE (1mg/.2 mg); Loestrin FE 24; and Ovcon 35. In each of these markets, Teva is one of a limited number of firms capable of developing a generic oral contraceptive product that would compete in that market, and is well-positioned to enter the markets in a timely manner.

- Both Teva and Barr are developing generic products equivalent to Ortho Tri-Cyclen Lo 28, and are among a limited number of firms with this product in development.

The complaint charges that entry into the above markets would not be timely or sufficient to deter or counteract the anticompetitive effects of the acquisition. The combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry

also would not be likely because many of the markets in question are relatively small and in decline, offering limited and insufficient sales opportunities to encourage new entry. The complaint also charges that the acquisition would harm to consumers in the above markets. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market, with prices decreasing with the entry of each additional competitor. Also, the complaint charges that the acquisition would increase both the likelihood of coordinated action by the remaining competitors in the above markets, and the likelihood that the combined entity would delay or forego the launch of new products into these markets. The consent order requires Teva and Barr to divest certain rights and assets related to the above products to a Commission-approved acquirer. The order requires Teva and Barr to provide transitional services to enable the acquirer to obtain all necessary FDA approvals.

King Pharmaceuticals, Inc./Alpharma, Inc., C-4246 (consent order issued February 2, 2009) (http://www.ftc.gov/enforcement/cases-proceedings/081-0240/king-pharmaceuticals-inc-alpharma-inc-matter). The complaint charges that King's acquisition of Alpharma would cause significant anticompetitive harm by eliminating competition between King and Alpharma in the market for oral long acting opioid analgesics ("oral LAOs"). The merging firms offer the only two competitively significant branded morphine sulphate oral LAOs, which are particularly close competitors within the larger oral LAO market. The complaint charges that the loss of head-to-head competition between King's Avinza and Alpharma's Kadian would likely result in higher prices for branded morphine sulphate oral LAOs. The complaint states that entry into the market for the manufacture and sale of oral LAOs is difficult, expensive, and time-consuming – obtaining FDA approval to make and sell oral LAOs takes at least two years – and would not offset the anticompetitive impact of the acquisition. The consent order requires King to divest Kadian to drug-manufacturer Actavis (which currently manufactures Kadian for King). Actavis, one of the world's largest generic drug companies, will continue to sell Kadian in competition with Avinza and other oral LAOs, and will now be able to introduce an "authorized" generic version of Kadian earlier than Kadian's 2010 patent expiration date. The consent order provides that, if the Commission later determines that Actavis is not an acceptable acquirer of Kadian, the parties will unwind the divestiture and then re-divest Kadian to another Commission-approved buyer within six months after the order becomes final.

Ovation Pharmaceuticals, Inc.; **Federal Trade Commission v. Lundbeck, Inc.** (See Section II A for citation and annotation.)

Sun Pharmaceuticals Industries/Taro Pharmaceutical Industries, C-4230 (consent order issued September 16, 2008) (http://www.ftc.gov/os/caselist/0710193/index.shtm). The complaint charged that Sun's acquisition of Taro would result in reduced competition and higher prices to consumers for three generic formulations of the anticonvulsant drug carbamazepine. The drugs named in the complaint were immediate-release carbamazepine tablets, chewable carbamazepine tablets, and extended-release carbamazepine tablets. The complaint alleged that the merger would reduce the number of firms producing the generic chewable tablet from three to two and reduce the number of firms producing the immediate-release form from four to three, leaving Teva as the only remaining significant competitor. In the market for the generic extended-release form, Sun and Taro were the only companies that had applied for FDA

approval to market the drug, and as a result, the merger would eliminate future competition completely. The order requires that Sun divest all of its rights and assets related to the development, manufacture, and marketing of the three generic carbamazepine drugs to Torrent Pharmaceutical Limited or another Commission approved buyer. The order also requires that Sun provide transitional services including help obtaining necessary FDA approvals and technical transfer assistance.

Schering-Plough Corporation/Organon BioSciences N.V., C-4211 (consent order issued December 28, 2007) (http://www.ftc.gov/os/caselist/0710132/index.shtm). The complaint charged that Schering's acquisition of Organon from Akzo-Nobel would harm competition in three highly concentrated markets for live poultry vaccines. According to the complaint, the merger created a monopoly in the market for vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus, and gave Schering-Plough a dominant share in the markets for live vaccines for the prevention and treatment of fowl cholera due to Pasteurella multocida, and live vaccines for the prevention and treatment of Mycoplasma gallisepticum in poultry. The order requires Schering-Plough to divest to the Fort Dodge division of Wyeth all of the assets, including research, development, customer, supplier and manufacturing contracts, and all intellectual property excluding trademarks, of its live vaccine for the Georgia 98 strain of infectious bronchitis and its live Mycoplasma gallisepticum vaccine, and Organon's live fowl cholera vaccine. The order also includes a supply and transition services agreement under which Schering-Plough will provide the vaccines for two years to Wyeth until Wyeth obtains the necessary regulatory approvals to bring the vaccines in-house.

Mylan Laboratories/E. Merck oHG., C-4200 (consent order issued November 1, 2007) (http://www.ftc.gov/os/caselist/0710164/0710164.shtm). The complaint charged that Mylan's acquisition of a generic subsidiary of Merck would result in reduced competition and higher prices to consumers for five generic drugs produced by both companies to treat hypertension and cardiac problems. The drugs named in the complaint were: acebutolol hydrochloride capsules (a beta blocker used to treat hypertension), flecainide acetate tablets (an anti-arrhythmia drug used to treat heart problems), guanfacine hydrochloride tablets (an alpha blocker used to treat hypertension), nicardipine hydrochloride capsules (a calcium channel blocker used to treat hypertension), and sotalol hydrochloride AF tablets (a beta blocker used to treat hypertension). Mylan and Merck, through an agreement with Par Pharmaceuticals, were the only two suppliers of generic acebutolol hydrochloride capsules, and among a small number of suppliers for the other four drugs. The order requires that Merck divest its assets in the five drugs to Amneal. The order also requires that Mylan and Merck provide transitional services to help Amneal obtain necessary FDA approvals.

Rite Aid Corp./The Jean Coutu Group, Inc., C-4191 (consent order issued September 17, 2007) (http://www.ftc.gov/os/caselist/0610257/0610257.shtm). The complaint charged that Rite Aid's acquisition of Brooks and Eckerd retail pharmacies from the Jean Coutu Group would substantially lessen competition in the retail sale of pharmacy services to cash customers in twenty-three local markets in Connecticut, New Hampshire, New York, New Jersey, Maryland, Maine, Pennsylvania, Vermont, and Virginia. Rite Aid and Brooks/Eckerd accounted for at least half (and up to 100%) of the pharmacies in each market. The complaint also alleged that the

merger would allow Rite Aid to unilaterally exercise market power in the retail sale of pharmacy services to cash customers, and make it likely that cash paying pharmacy customers would pay higher prices in those markets. According to the complaint, the market for sales of pharmacy services to cash customers is separate from the market for sale of pharmacy services to customers covered by third party payers. The order requires Rite Aid to divest one store in each of the twenty-three markets to a Commission-approved buyer. The order also contains an asset maintenance agreement requiring the respondents to preserve the viability and competitiveness of the drug stores to be divested, a provision that allows the Commission to appoint a trustee if the required divestitures are not completed as required by the order, and a ten-year prior notice requirement for the acquisition of any store within five miles of any of the divested pharmacies.

Activas Group/Abrika Pharmaceuticals, Inc., C-4190 (consent order issued May 18, 2007) (http://www.ftc.gov/os/caselist/0710063/index.shtm). The complaint alleged that the merger of Actavis and Abrika would create a monopoly in the market for generic isradipine capsules and allow Actavis to exercise its unilateral market power to increase prices. Isradipine is used for the treatment of hypertension, ischemia, and depression. The order requires Activas to divest certain rights and assets related to generic isradipine capsules to Cobalt Laboratories, Inc. within ten days of the acquisition, and to transfer its supply arrangement for generic isradipine to Cobalt.

Hospira, Inc./Mayne Pharma Limited, C-4182 (consent order issued January 18, 2007) (http://www.ftc.gov/enforcement/cases-proceedings/0710002/hospira-inc-mayne-pharma-limited-matter). The complaint alleged that Hospira's acquisition of Mayne would reduce current horizontal competition or potential competition in already concentrated markets for five generic injectable drugs. According to the complaint, the number of generic suppliers has a direct and substantial effect on generic pricing in markets where there are a limited number of competing suppliers, because each additional supplier can have a competitive impact on the market. The drugs named in the complaint were: hydromorphone hydrochloride, nalbuphine hydrochloride, morphine sulfate, and preservative-free morphine, analgesics used to treat moderate to severe pain; and deferoxamine mesylate, an iron chelator used to treat acute iron poisoning or chronic iron overload. Hospira and Mayne were two of only three suppliers of hydromorphone hydrochloride in the U.S. market. In the markets for nalbuphine hydrochloride, morphine sulfate, preservative-free morphine and deferoxamine mesylate, Hospira was either the only supplier or one of a small number of suppliers, and Mayne was one of a limited number of suppliers in the process of entering these markets. The order requires the divestiture of Mayne's hydromorphone hydrochloride, nalbuphine hydrochloride, morphine sulfate, preservative-free morphine and deferoxamine mesylate assets to Barr.

Johnson & Johnson/Pfizer, C-4180 (consent order issued January 16, 2007) (http://www.ftc.gov/os/caselist/0610220/0610220.shtm). The Commission's complaint charged that Johnson & Johnson's acquisition of Pfizer's Consumer Healthcare business would increase concentration and reduce competition in the U.S. markets for four over-the-counter drugs. According to the complaint, the acquisition would have enabled Johnson & Johnson to raise prices and reduce the incentive to innovate and develop new products in the four markets:

■ *Over-the-counter H-2 blockers*. H-2 blockers are used to prevent and relieve heartburn associated with acid indigestion. Johnson & Johnson's Pepcid and Pfizer's Zantac accounted for over 70% of sales in the highly concentrated H-2 blocker market. The order requires the divestiture of Pfizer's Zantac assets to Boehringer. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Boehringer.

■ *Over-the-counter* hydrocortisone *anti-itch products*. Hydrocortisone anti-itch products are topical medications used to treat minor skin irritations and inflamations. Johnson & Johnson's Cortaid product and Pfizer's Cortizone product accounted for over 55% of sales in a highly concentrated market. The order requires the divestiture of Pfizer's Cortizone product to Chattem. The order also contains provisions to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem.

■ *Over-the-counter night-time sleep aids*. Night-time sleep aids are used for the relief of occasional sleeplessness by individuals who have difficulty falling asleep. Johnson & Johnson's Simply Sleep product and Pfizer's Unisom product accounted for over 45% of sales in a highly concentrated market. The order requires the divestiture of Pfizer's Unisom sleep-aid assets to Chattem. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem.

■ *Over-the-counter diaper rash treatments*. Diaper rash treatments are creams or ointments that are available without a prescription for the prevention and treatment of diaper rash. Johnson & Johnson's Balmex product and Pfizer's Desitin products accounted for approximately 50% of sales in a highly concentrated market. The order requires the divestiture of Johnson & Johnson's Balmex diaper rash treatment product to Chattem. The order also contains provisions concerning to ensure that the divestiture is successful, and that the viability of the divested assets is maintained until they are transferred to Chattem.

Watson Pharmaceuticals Inc./Andrx Corp., C-4172 (consent order issued December 6, 2006) (http://www.ftc.gov/os/caselist/0610139/index.htm). The complaint alleged that Watson's acquisition of Andrx substantially lessened actual, potential, and future competition in thirteen separate markets for generic pharmaceutical products, and increased the likelihood that consumers would be forced to pay higher prices.

■ *Generic hydrocodone bitartrate/ibuprofen tablets*. Hydrocodone bitartrate/ibuprofen is a combination analgesic and anti-inflammatory drug used for the short-term management of acute pain. Watson, under a marketing agreement with Interpharm, and Andrx were two of three suppliers of generic hydrocodone bitartrate/ibuprofen. The order requires Watson to terminate its marketing agreement with Interpharm, and return all of the Watson rights and assets necessary to market generic hydrocodone bitartrate/ibuprofen tablets back to Interpharm.

■ *Generic glipizide ER tablets*. Glipizide ER is used in the treatment of type 2 diabetes to stimulate the release of insulin and reduce blood sugar levels in the body. The acquisition would have increased Watson's market share to over 80% and left only one other U.S. supplier of generic glipizide ER. The order requires the divestiture of the Andrx rights and assets necessary to develop, manufacture, and market generic glipizide ER tablets to Actavis Elizabeth LLC.

■ *Generic oral contraceptives*. Andrx and Teva had a marketing agreement under which Teva marketed eleven oral contraceptives for Andrx. In each of the markets, Watson and Andrx/Teva were among a limited number of current suppliers or potential entrants. In the markets for branded Ortho-Cyclen and Ortho Tri-Cyclen, the acquisition would have resulted in only one other generic supplier in each market. Watson was one of two or three generic suppliers in seven additional markets for Ortho-Cept, Triphasil 28, Alesse, Ortho-Novum1/35, Ortho-Novum 7/7/7, Loestrin FE (1mg/0.020 mg), and Loestrin FE (1.5mg/0.030 mg), in which Andrx/Teva were developing competitive generic products. In addition, both Watson and Andrx/Teva were in the process of developing generic equivalents of Mircette tablets and generic Ovcon-35 tablets. The order requires the divestiture of the Andrx rights and assets to the eleven general oral contraceptives to Teva, and requires Andrx to supply Teva with the products for five years in order to provide Teva with the time needed to gain FDA approval to manufacture and sell the drugs.

Barr Pharmaceuticals Inc./Pliva., C-4171 (consent order issued December 8, 2006) (http://www.ftc.gov/enforcement/cases-proceedings/0610217/barr-pharmaceuticals-inc-matter). The Commission's complaint charged that Barr's $2.5 billion acquisition of Pliva would have eliminated current or potential competition in the product markets for three generic drugs and the market for organ preservation solutions higher prices.

■ *Generic trazodone hydrochloride.* Trazodone is an antidepressant that is supplied by five companies. Barr and Pliva were two of three suppliers of the 150 mg formulation. The acquisition would have increased Barr's overall market share in all formulations to 64%. The order requires the divestiture of Barr's trazodone hydrochloride assets to Apotex, and requires Barr to provide Apotex with various transitional services until Apotex obtains FDA approval to manufacture trazodone hydrochloride itself.

■ *Generic Triamterene/HCTZ.* Triamterene/HCTZ is used in the treatment of high blood pressure. The acquisition would have reduced the number of suppliers from five to four and increased Barr's market share to 35%. The order requires the divestiture of Barr's triamterene/HCTZ assets to Apotex, and requires Barr to provide Apotex with various transitional services until Apotex obtains FDA approval to manufacture triamterene/HCTZ itself.

■ *Generic nimodipine.* Nimodipine is used to treat symptoms resulting from a ruptured blood vessel in the brain. The patent on the branded product had expired and there were currently no generic versions on the market. The merger would have eliminated potential competition between Barr and Pliva, the only companies seeking approval to offer generic nimodipine. The order requires the divestiture of Pliva's nimodipine assets to Banner within ten

days of the acquisition, or Barr's nimodipine assets to Cardinal within sixty days of the acquisition.

■ *Organ preservation solutions*. These solutions are used during the harvesting of donor organs to preserve them prior to transplant. Barr and Pliva accounted for approximately 90% of the market. The order requires the divestiture of Pliva's organ preservation solution business to New Custodial, a company formed for the purpose of marketing and selling Pliva's organ preservation solution product.

Teva Pharmaceutical Industries and IVAX Corporation, C-4155 (consent order issued March 2, 2006) (http://www.ftc.gov/enforcement/cases-proceedings/051-0214/teva-pharmaceutical-industries-ltd-ivax-corporation-matter). The complaint alleged that Teva's $7.4 billion acquisition of IVAX would lessen current and/or future competition between the two companies in fifteen highly concentrated markets for generic pharmaceuticals, and result in the delay or elimination of additional price competition or higher prices for consumers:

■ *Generic amoxicillin clavulanate potassium*. Amoxicillin clavulanate is a penicillin antibiotic. Teva, IVAX, Sandoz and Ranbaxy were the only suppliers of amoxicillin clavulanate in the U.S. The merger would increase Teva's market share for all formulations to over 50%, and leave Teva the only supplier of the 600 mg powder formulation. The order requires the divestiture of IVAX's amoxicillin clavulanate potassium assets to Par.

■ *Cefaclor LA tablets*. Cefaclor tablets LA tablets are a cephalosporin antibiotic. As Teva and IVAX were the only competitors in this market, the merger would create a monopoly. The order requires the divestiture of IVAX's cefaclor LA tablets to Par.

■ *Pergolide mesylate tablets.* Pergolide mesylate tablets are used to treat Parkinson's disease. Teva and IVAX were the only competitors in this market. The order requires the divestiture of Teva's Pergolide mesylate tablets to Par.

■ *Estazolam tablets (used to treat seizure disorders).* Teva (with 52% of the market), IVAX (with 13% of the market) and Watson were the only suppliers of generic estazolam tablets in the U.S. The order requires the divestiture of Teva's estazolam tablets to Par.

■ *Leuprolide acetate*. Leuprolide acetate is an injectable drug used to treat prostate cancer. Teva, (with a 50% market share), IVAX and Sandoz were the only three companies in the market. The order requires the divestiture of IVAX's leuprolide acetate injection kits to Par.

■ *Nabumetone tablets*. Nabumetone tablets are used to treat inflamation. Teva, the leading supplier had a 60% market share. IVAX and Sandoz were the only other companies in the market. The order requires the divestiture of IVAX's nabumetone tablets to Par.

■ *Amoxicillin*. Amoxicillin is a penicillin antibiotic used to treat infections. Although five companies supplied various formulations of the drug, only Teva, IVAX and

Ranbaxy supplied the 200 mg and 400 mg oral suspensions and the 875 mg tablet formulations. The order requires the divestiture of IVAX's amoxicillin to Par.

■ *Propoxyphene hydrochloride capsules*. Propoxyphene hydrochloride capsules are analgesics. Teva, IVAX, Mylan and Qualitest were the only suppliers in the market. The order requires the divestiture of IVAX's propoxyphene hydrochloride capsules to Par.

■ *Nicardipine hydrochloride capsules*. Nicardipine hydrochloride capsules are used to treat heart conditions. Teva, IVAX, Mylan and Par were the only suppliers in the market. The order requires the divestiture of IVAX's nicardipine hydrochloride capsules to Barr.

■ *Flutamide capsules*. Flutamide capsules are used in the treatment of cancer. After the acquisition, Teva (with 62% of the market), Sandoz and Barr would be the only suppliers of flutamide capsules in the U.S. The order requires the divestiture of Teva's flutamide capsules to Par.

■ *Clozapine tablets*. Clozapine tablets are used in the treatment of psychotic and maniacal disorders. IVAX, Mylan and Caraco were the only suppliers in the U.S. Teva, however, had obtained FDA approval and recently begun supplying clozapine to some of its customers. The order requires the divestiture of Teva's clozapine tablets to Par.

■ *Tramadol/acetaminopen tablets*. IVAX, Par and Caraco (a recent entrant) were the only suppliers in the U.S. Teva was in the process of entering the market and was the only other supplier capable of entering the market in a timely fashion. The order requires the divestiture of Teva's tramadol/acetaminopen tablets to Barr.

■ *Glipizide and metformin hydrochloride tablets*. Glipizide and metformin hydrochloride tablets are blood glucose regulators used to treat type II diabetes. Teva and Sandoz were the only suppliers and IVAX was one of a small number of suppliers capable of entering the market in a timely manner. The order requires the divestiture of IVAX's glipizide and metformin hydrochloride tablets to Barr.

■ *Calcitrol injectables*. Calcitrol is an injectable form of vitamin D used by dialysis patients. Teva and American Pharmaceutical Partners were the only suppliers in the U.S. market. IVAX, through a distribution agreement with Genix Therapeutics, was the only supplier capable of entering the market in a timely fashion. The order requires the divestiture of IVAX's calcitrol injectables to Par.

■ *Cabergoline tablets*. Cabergoline tablets are used in the treatment of Parkinson's disease. Teva and IVAX were two of a small number of suppliers capable of entering the market when Pfizer's patent for the branded product Dostinex expired in December, 2005. The order requires the divestiture of Teva's cabergoline tablets to Barr.

Novartis AG, 140 F.T.C. 480 (2005) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume140.pdf#page=486). The complaint alleged that

Novartis AG's acquisition of EON Labs would lessen competition and result in higher prices in the markets for three generic drugs. According to the complaint, the generic forms of these drugs constituted the appropriate product market under which to analyze the merger because the branded drug did not effect the pricing of the generic. Novartis and Eon were significant competitors in the markets for generic desipramine hydrochloride tablets (a tricyclic antidepressant), generic orphenadrine citrate ER tablets (a muscle relaxant), and generic rifampin oral capsules (used in the treatment of tuberculosis).

- *Generic desipramine hydrochloride tablets*. Prior to the acquisition, only Novartis and Eon marketed all six strengths of generic desipramine hydrochloride tablets in the U.S. The sole other competitor, Watson Pharmaceuticals, marketed only three of the six strengths. After the acquisition, Novartis would account for more than95% of all generic desipramine hydrochloride tablets sold in the U.S. The order requires the divestiture of Eon's desipramine hydrochloride assets to Amide. The order also requires Novartis to enter into a supply agreement with Amide until Amide gains FDA approval to manufacture the drugs on its own.

- *Generic orphenadrine citrate ER tablets*. Prior to the acquisition, Novartis, Eon, and Impax manufactured and marketed generic orphenadrine citrate ER tablets in the U.S. After the acquisition Novartis would account for 70% of U.S. sales. The proposed order requires the divestiture of Novartis' orphenadrine citrate ER tablets to Amide. The order also requires Novartis to enter into a supply agreement with Amide until Amide gains FDA approval to manufacture the drugs on its own.

- *Generic rifampin oral capsules*. Novartis, Eon, and VersaPharm manufactured and marketed generic rifampin oral capsules in the U.S. After the acquisition, Novartis would account for 70% of U.S. sales. The order requires the divestiture of Novartis' generic rifampin oral capsules assets to Amide, which currently contract manufactures rifampin for Novartis.

Genzyme Corporation/Ilex Oncology, 139 F.T.C. 49 (2005) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume139.pdf#page=54). The complaint alleged that the merger of Genzyme and Ilex eliminated competition in the market for immunosuppressant drugs used in solid organ transplants (SOT). SOT acute therapy drugs are used in solid organ transplants to suppress the transplant recipient's immune system. Genzyme, the leading supplier of SOT acute therapy drugs, marketed Thymoglobulin. Ilex's Campath, a new entrant into the market, was an especially close competitor to Thymoglobulin due to its similar mechanisms of action. According to the complaint the other four immunosuppressant drugs on the market were not substitutes for Genzyme's and Ilex's SOT acute therapy drugs because of different mechanisms of action. The order requires Genzyme to divest its contractual and decision making rights, including its portion of the earnings from sales of Campath, to Schering, which already markets and distributes Campath in the U.S. The order also appointed a monitor to oversee the divestiture of Campath earnings from solid organ transplant sales.

Sanofi-Synthelabo/Aventis, 138 F.T.C. 478 (2004) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume138.pdf#page=483). The complaint alleged that

the merger of two large French pharmaceutical companies would lessen competition in three pharmaceutical markets in the United States and increase the likelihood that consumers would be forced to pay higher prices:

■ *Factor Xa Inhibitors*. Factor Xa inhibitors are anticoagulent products used to treat conditions related to excessive blood clot formation. Sanofi and Aventis were the only two companies positioned to successfully compete in the market for factor Xa inhibitors. Lovenox, manufactured by Aventis, accounted for 92% of factor Xa inhibitor sales in the U.S. Sanofi manufactured Arixtra, a recent entrant to the market. The order requires that Sanofi: (1) divest Arixtra to Glaxo; (2) transfer manufacturing facilities used to produce Arixtra to Glaxo; (3) contract manufacture certain ingredients until Glaxo can obtain the necessary regulatory approvals and supply sources to make the ingredients; and (4) help Glaxo complete three clinical trials.

■ *Cytotoxic Colorectal Cancer Drugs*. Cytotoxic drugs are used in the treatment of colorectal cancer. Sanofi's Eloxatin and Camptosar (irinotecan), which was manufactured by Yakult Honsha and marketed in the U.S. by Pfizer, accounted for over 80% of the U.S. market. Aventis did not market a similar drug in the U.S., but licensed irinotecan under the brand name Campto from Yakult for sale in other territories. In addition, through contractual relationships with Pfizer, Aventis shared the results of key clinical trials with Pfizer, and possessed a number of U.S. patents relating to Camptosaur. According to the complaint, the merger gave Sanofi access to Camptosar's pricing, forecasts, and marketing strategy, which would result in diluted competition between Sanofi and Pfizer. The order includes provisions that require the parties to divest to Pfizer key clinical studies for Campto that Aventis is currently conducting, certain U.S. patents and other assets related to areas where Pfizer markets Camptosar.

■ *Prescription Insomnia Treatments*. Sanofi's Ambien accounted for over 85% of the U.S. market for prescription insomnia treatments. Sepracor planned to enter this market within nine months as a competitor to Sanofi with its product Estorra, which is licensed to Sepracor from Aventis. Under the licensing agreement, Aventis is entitled to royalty payments based on Estorra sales. After the acquisition Sanofi would control the leading product in the market and have a financial stake in what is likely to be its main competitor. The order requires the parties to divest Aventis' contractual rights to Estorra, either to Sepracor or a third party approved by the FTC.

Pfizer Inc./Pharmacia Corporation, 135 F.T.C. 608 (2003) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume135.pdf#page=613). The complaint alleged that Pfizer's $60 billion acquisition of Pharmacia would lessen direct or potential competition between the two companies in nine highly concentrated markets, and result in the delay or elimination of additional price competition or higher prices for consumers:

■ *Extended Release Treatments for Overactive Bladder (OAB).* Pharmacia's Detrol and Detrol LA and Johnson & Johnson's Ditropan XL were the only two extended release OAB products marketed in the U.S. Pfizer, one of two companies best-positioned to enter the market within the next two years, was in the process of seeking FDA approval for darifenacin, its

extended release OAB product. The complaint alleged that the merger would eliminate potential competition between Pharmacia and Pfizer and increase the likelihood that Pfizer would delay the launch of darifenacin. The order requires Pfizer to divest darifenacin and certain other assets to Novartis AG and contains other provisions to ensure that the divestiture is successful.

■ *Combination Hormone Replacement Therapies (HRT).* Pfizer's femhrt and Pharmacia's Activella were two of the three leading combination HRT products marketed in the U.S. After the merger, Pfizer and Wyeth, the other leading competitor, would control approximately 94% of the HRT market. The order requires the divestiture of Pfizer's femhrt to Galen Holdings plc, and contains other provisions to ensure that the divestiture is successful.

■ *Treatments for Erectile Dysfunction (ED).* With over 95% of the U.S. ED market and a second generation Viagra-like product in development, Pfizer dominated the research, development, manufacture and sales of prescription drugs for ED. Pharmacia, Pfizer's only significant potential competitor, had two products, IN APO and PNU-142,774, in clinical development. The order requires Pharmacia to return all of its rights for IN APO to Nastech Pharmaceutical Company, and to divest all of its rights and interests for the field of human sexual for PNU-142,774 to Neurocrine Biosciences, Inc. The order also contains other provisions to ensure that the divestiture is successful.

■ *Drugs for Canine Arthritis.* Three companies sold prescription drugs for the treatment of canine arthritis: Pfizer's product, Rimadyl, accounted for 70% of the market and Wyeth's product, EtoGesic, accounted for 30% of the market. Novartis began marketing Deramaxx in early 2003 under a licensing agreement with Pharmacia, which currently manufactured Deramaxx, and supplied it to Novartis. The complaint alleged that because of its license and supply agreement with Novartis, Pfizer, the leading competitor in the market, would control the manufacturing and supply of the competing product Deramaxx, and under the existing licensing agreement, have access to Novartis' sensitive confidential information on Deramaxx's pricing, forecasts, and marketing strategy. The order requires Pharmacia to renegotiate its license and supply agreement with Novartis to allow Novartis to operate as an independent competitor by eliminating the control Pfizer would have over Novartis's product, restricting the type of information Pfizer would be able to obtain about Deramaxx, and allowing Novartis to compete with Pfizer in the development of a second generation canine arthritis product.

■ *Antibiotic Treatments for Lactating Cow Mastitis and Dry Cow Mastitis.* Pfizer, Pharmacia and Wyeth were the only significant competitors in the markets for lactating cow and dry cow mastitis antibiotic products. After the merger Pfizer and Pharmacia would account for 50% of the sales of lactating cow mastitis products and 55% of the sales of dry cow mastitis products. The order requires Pfizer to divest all of its U.S. rights to its bovine mastitis antibiotic products to Schering-Plough Corporation.

■ *Over-the-Counter Hydrocortisone Creams and Ointments.* Pfizer's Cortizone brand and Pharmacia's Cortaid brand were the only two branded hydrocortisone creams on the

U.S. market, and accounted for 55% of the over-the-counter sales of hydrocortisone creams and ointments. The order requires Pharmacia to divest its Cortaid business to Johnson and Johnson.

■ *Over-the-Counter Motion Sickness Medications.* Pfizer, with its Bonine product and Pharmacia, with its Dramamine product were the two leading suppliers in this market and accounted for a combined market share of 77%. The order requires Pfizer to divest its U.S. and Puerto Rican Bonine assets to Insight Pharmaceuticals Corporation.

■ *Over-the Counter Cough Drops.* Pfizer, with its Halls brand and Pharmacia, with its Ludens brand, were the only two significant competitors in the over-the-counter cough drops market. The order requires Pfizer to divest its Halls cough drop business to Cadbury Schweppes.

Baxter International Inc./Wyeth Corporation, 135 F.T.C. 49 (2003) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume135.pdf#page=54). The Commission's complaint charged that Baxter's acquisition of the generic injectable drug business from Wyeth's subsidiary, ESI Lederle, would reduce either current horizontal competition or potential competition in the market for five injectable drugs:

■ *Propofol.* Baxter, under a supply agreement with GenesiaSicor, marketed the only generic version of AstraZeneca's branded propofol Diprivan, an anesthetic preferred for outpatient surgery because of its short duration profile. Wyeth was in the process of seeking FDA approval and was one of two companies most likely to enter the market with its own generic version. The complaint alleged that new entry would be difficult and lengthy. Among other things, the preservatives used in the Baxter marketed propofol and in AstraZeneca's product are patent protected and the manufacturing process complex. In order to preserve the future competition and probable lower prices in the market that would have resulted from the entry of a Wyeth generic propofol, the order required the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company, as well as other requirements to ensure the success of the divestiture.

■ *Pancuronium.* In the market for pancuronium, a long-acting neuromuscular blocking agent used to freeze muscles during surgery and for patients who are mechanically ventilated, Baxter (under an exclusive marketing agreement with GenesiaSicor), along with Wyeth, and Abbott were the only suppliers. The complaint alleged that the acquisition would have reduced the number of competitors from three to two, leaving Baxter and Wyeth with a combined market share of 74% after the acquisition. New entry was unlikely because pancuronium was an older drug with limited usage. The order required Baxter to divest its pancuronium assets to GenesiaSicor.

■ *Vecuronium.* Wyeth discontinued its production of vecuronium, an intermediate-acting neuromuscular blocking agent used during surgery or ventilation, in 2001, but planned to re-launch the product. Prior to stopping production, Baxter (under an exclusive supply agreement with GenesiaSicor) and Wyeth were the two largest of five vecuronium suppliers and held a 53% combined market share. The complaint charged that the acquisition would eliminate

the price competition that would have resulted when Wyeth reentered the market. The order requires Baxter to divest its vecuronium assets to GenesiaSicor.

■ *Metoclopramide.* The acquisition would have combined two of four companies supplying metoclopramide, an antiemetic used in certain types of chemotherapy and other post-operative treatments. Wyeth, manufacturer of the branded version of metoclopramide, and Baxter, the exclusive supplier of GenesiaSicor's generic metoclopramide drug, together accounted for over half of the U.S. market. The order requires Baxter to terminate its interests in and divest its assets to GenesiaSicor.

■ *New Injectable Iron Replacement Therapies (NIIRTs).* The complaint alleged harm to potential competition and/or price competition in the market for NIIRTs, including both iron gluconate and iron sucrose, which are used to treat iron deficiency in hemodialysis patients. Baxter and Watson jointly marketed Ferrlecit, one of only two NIIRT's approved for sale in the U.S. Wyeth was the best positioned firm to successfully enter the market. The complaint charged that entry was difficult and lengthy. Among other things, a lack of raw material suppliers and complex manufacturing processes complicate entry. The order requires Baxter to terminate its co-marketing agreement with Watson and provides incentives for Baxter to proceed with development of Wyeth's iron gluconate product.

Amgen Inc./Immunex Corporation, 134 F.T.C. 333 (2002) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume134.pdf#page=337). The complaint alleged that Amgen's $16 billion acquisition of Immunex would lessen direct or potential competition in three highly concentrated biopharmaceutical markets:

■ *Neutrophil Regeneration Factors.* Amgen's Neupogen and Neulasta and Immunex's Leukine were the only neutrophil regeneration factors approved by the FDA for sale in the U.S. Neutrophil regeneration factors are used to help the immune systems of chemotherapy patients by increasing the production of two types of white blood cells. The order requires that Immunex divest its Leukine product to Schering AG.

■ *TNF Inhibitors.* TNF inhibitors are used to treat inflamation in patients having autoimmune diseases by preventing the binding of TNF (a cytokine that promotes inflamation) receptors and proteins. Immunex was one of two companies that marketed TNF inhibitors in the U.S. Amgen, one of three companies that had TNF inhibitors in clinical development for sale in the U.S., planned to launch its product in 2005. The order requires that Amgen license certain patents to Sereno, a Swiss company developing a TNF inhibitor for use in Europe, that block Sereno's ability to market in the U.S.

■ *IL-1 Inhibitors.* IL-1 inhibitors are also used to treat inflamation in patients with autoimmune diseases. Amgen manufactured the only IL-1 inhibitor on the market in the U.S. Immunex and Regeneron were the only companies with IL-1 inhibitors in clinical trials; Immunex, however, held several patents that could delay or stop the development and marketing of Regeneron's IL-1 inhibitor. The order requires that Immunex license certain patents to Regeneron that will allow it to develop and bring its product to market.

The Hearst Trust, et. al., Civil Action No. 1:01CV00734 (D.D.C. filed April 5, 2001) (http://www.ftc.gov/enforcement/cases-proceedings/9910323a/hearst-trust-hearst-corporation-first-databank-inc); Civil Action No. 1:01CV02119 (D.D.C. filed October 11, 2001) (civil penalty action); (http://www.ftc.gov/enforcement/cases-proceedings/9910323b/hearst-trust-hearst-corporation-us-ftc). In a complaint filed in U.S. District Court for the District of Columbia, the Commission charged Hearst and its wholly owned subsidiary, First DataBank Inc., with illegally acquiring a monopoly in the market for electronic integratable drug information databases, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. According to the complaint, the 1998 acquisition of Medi-Span, Inc., allowed First DataBank to institute substantial price increases to its customers for use of the electronic databases which contain clinical, pricing and other information on prescription and non-prescription drugs. The complaint also charged Hearst with violating Section 7A (a) of the Clayton Act, by illegally withholding certain 4(c) documents about the Medi-Span acquisition that were required for pre-merger notification review under the Hart-Scott-Rodino Act. The complaint asked the Court to order Hearst to create and divest a new competitor to replace Medi-Span, and to disgorge the illegally gained profits from the anticompetitive price increases. On December 14, 2001, the Commission voted to approve a proposed settlement that required Hearst to divest the former Medi-Span to Facts and Comparisons and to pay $19 million in disgorgement of illegal profits to its customers. Commissioners Leary and Swindle issued dissenting statements concerning the disgorgement portion of the order. The district court approved the final order and stipulated permanent injunction on December 18, 2001. The Commission also asked the Department of Justice to file a separate complaint in U.S. District Court seeking civil penalties for Hearst's failure to comply with pre-merger notification reporting requirements. In a final judgment filed on October 11, 2001, Hearst agreed to pay $4 million in civil penalties. On January 9, 2002, the Commission filed a brief as intervenor opposing the private class plaintiffs' petition for an award of $5 million in attorney fees which represented 22% of the total direct purchaser settlement payment of $24 million. The Commission argued that private counsels' fees should be reduced to reflect the minimal legal work and limited incremental value that the private attorneys contributed to the settlement after the Commission had reached a tentative settlement with the parties of $16 million. On May 21, 2002, the District court ruled that the private attorneys were only entitled to a percentage of the settlement attributable to their efforts in the litigation and reduced their award to $2.4 million.

Glaxo Wellcome plc/SmithKline Beecham plc, 131 F.T.C. 56 (2001) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume131.pdf#page=61). The Commission's complaint charged that the merger of Glaxo Wellcome (Glaxo) and SmithKline Beecham (SB) would create the world's largest research-based pharmaceutical manufacturer, substantially lessen competition in nine separate pharmaceutical markets, and result in fewer consumer choices, higher prices and less innovation. In six markets the order required divestiture:

- *5HT-3 Antiemetic Drugs.* Glaxo and SB accounted for 90% of the sales of new generation drugs used in chemotherapy to reduce the incidence of side effects. The order required the divestiture of the worldwide rights of SB's drug Kytril to F. Hoffman LaRoche.

■ *Injectable Antibiotic Ceftazidime.* Glaxo and SB were the only two manufacturers of ceftazidime, and Glaxo was the largest of three firms marketing ceftazidime. The order required the divestiture of SB's U.S. rights to manufacture and market ceftazidime to Abbott Laboratories.

■ *Oral and Antiviral Drugs for the Treatment of Herpes, Chicken Pox and Shingles.* Glaxo's Valtrex and SB's Famvir were the only second-generation antiviral prescription drugs available on the market, and no other companies have similar products in development. The order required the divestiture of SB's antiviral drug Famvir to Novartis.

■ *Topical Antiviral Drugs for the Treatment of Herpes Cold Sores.* SB's Denavir was the only FDA approved prescription topical antiviral drug sold in the US, and Glaxo, the only potential entrant into the market, was seeking FDA approval to market its European antiviral Zovirex in the U.S. The order required SB to divest Denavir to Novartis.

■ *Prophylactic Vaccines for the Treatment of Herpes.* Glaxo and SB were the leading two of only a few firms pursuing the development of a preventative vaccine. The order required Glaxo to return to its British collaborator, Cantab Pharmaceuticals, all rights to its technology for the development of a prophylactic herpes vaccine.

■ *Over-the Counter H-2 Blocker Acid Relief Products.* Glaxo's Zantac 75 and SB's Tagamet were two of the four branded OTC H-2 acid blockers on the market. The order required the divestiture of Glaxo's U.S. and Canadian Zantac trademark rights to Pfizer.

In three markets the order addressed competitive overlaps with other research and development firms where the merger was likely to result in delay, termination, or failure to develop as a competitor:

■ *Topoisomerase I Inhibitor Drugs Used to Treat Certain Tumors.* SB's Hycamptin was a second line therapy for non-small cell lung cancers and SB was developing a firstline therapy for colorectal and other solid-tumor cancers. Glaxo, through a collaboration with Gilead Sciences, was developing a drug, GI147211C, which would have been in direct competition with SB's Hycamptin. Only one other company manufactured similar anti tumor drugs. The order required Glaxo to assign all of its relevant intellectual property rights and relinquish all of Glaxo's reversionary rights to GI147211C to Gilead Sciences.

■ *Migraine Headache Treatment Drugs.* Glaxo's Immitrex and Amerge were the leading sellers of triptan drugs for the treatment of migraine headache. SB had an interest in another triptan drug, frovatriptan, which was being developed and scheduled for launch by Vernalis Ltd. in the second half of 2001. The order required SB to assign all of its intellectual property rights and relinquish all options to regain control over frovatriptan to Vernalis Ltd.

■ *Drugs to Treat Irritable Bowel Syndrome.* Glaxo owned and was conducting clinical trials on Lotronex, which had been taken off the market because of possible side effects. SB had an option to acquire and market renzapride which was being developed by the British

firm Alizyme Therapeutics plc. Because the merger would eliminate one of the few efforts underway to develop a drug for the treatment of irritable bowel syndrome, the order required SB to assign all of its intellectual property rights and relinquish all options to regain control over renzapride to Alizyme.

After the Commission issued the proposed consent agreement, the Commission continued to investigate the potential effects of the merger in the smoking cessation products market where Glaxo sold the prescription drug Zyban, and SB marketed Nicoderm and Nicorette, two over-the-counter nicotine replacement products. On January 23, 2001, the Commission closed the smoking cessation products investigation.

Pfizer Inc./Warner-Lambert Company, C-3957 (consent order issued July 27, 2000) (http://www.ftc.gov/enforcement/cases-proceedings/0010059/pfizer-inc-warner-lambert-company). The complaint alleged that Pfizer's acquisition of Warner-Lambert Company would lessen competition in four pharmaceutical markets:

- *Antidepressant Drugs Called Selective Serotonin Reuptake Inhibitors (SSRIs) and Selective Norepinephrine Reuptake Inhibitors (SNRIs).* Pfizer manufactured Zoloft, the second largest selling SSRI, and Warner and Forest Laboratories co-promoted Celexa, the fastest-growing SSRI. The order required Warner to end its co-promotion agreement with Forest, return all confidential information regarding Celexa to Forest, maintain the confidentiality of all Celexa marketing information, and prohibited former Warner sales employees involved in marketing Celexa from selling Zoloft until March 2001.

- *Pediculicides or Treatments for Head Lice Infestation.* Pfizer and Warner were the two largest manufacturers and accounted for approximately 60% of the market. The order required Pfizer to divest its brand RID to Bayer Corporation.

- *Drugs for Treating Alzheimer's Disease.* Pfizer's Aricept and Warner's Cognex were the only two drugs sold in the U.S. for the treatment of Alzheimer's disease. The order required the divestiture of Cognex to First Horizon.

- *EGFr-tk Inhibitors (drugs used to treat solid tumor cancers).* Pfizer and Warner were the two most advanced among four companies developing EGFr-tk inhibitors. The order required Pfizer to return its EGFr-tk inhibitor, CP-358,774, along with its technology and knowhow assets to its development partner OSI, to grant OSI an irrevocable worldwide license to its rights and patents jointly owned with Pfizer, to provide OSI with a manufacturing and supply agreement for the continued supply of CP-358,774 until the transfer of the manufacturing technology to a new manufacturer, and to pay OSIs costs for completing clinical trials on the drug. The order also provided for the appointment of an interim trustee to ensure that the development of CP-358,774 is maintained in the future.

Cardinal Health, Inc./ McKesson Corp., 12 F. Supp. 2d 34 (D.D.C. 1998) (http://www.ftc.gov/enforcement/cases-proceedings/9810025/mckesson-corp-amerisource-health-corp). 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.

Roche Holding Ltd., 125 F.T.C. 919 (1998) (consent order) (http://www.ftc.gov/enforcement/cases-proceedings/9710103/roche-holding-ltd-matter). The complaint charged that Roche's proposed $11 billion acquisition of Corange Limited would harm competition in two U.S. markets:

- *Thrombolytic agents* are given to heart attack victims as soon as possible after the onset of symptoms in order to dissolve blood clots. 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 were no competitive substitutes for thrombolytic agents, and only one other significantly less effective thrombolytic agent was approved for use in the United States.
- *DAT reagents* 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. The 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 used 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 order required Roche to divest or license all of the assets relating to Corange/Boehringer Mannheim's U.S. 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, and to grant to the purchaser an exclusive, world-wide royalty-free license for DAT reagents. Although the divestitures took place within the required time, the Commission included a "crown jewel" provision that would have required a larger asset divestiture had the more narrowly tailored divestiture not occurred.

American Home Products Corporation, 123 F.T.C. 1279 (1997) (http://www.ftc.gov/os/caselist/c3740.shtm). The complaint 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; that all three markets were highly concentrated; and that entry into each market was difficult and time consuming, with a number of broad patents governing the manufacture of the three products compounding the difficulty of new entry. The order 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. The order also included provisions protecting Schering-Plough from patent infringement lawsuits relating to the three vaccines.

Baxter International, Inc., 123 F.T.C. 904 (1997) (consent order) (http://www.ftc.gov/os/caselist/c3726.shtm). The complaint alleged that 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 complaint alleged that competition in two plasma products where entry was difficult and time consuming would be harmed : 1) the market for Factor VIII inhibitors for hemophiliacs, which was highly concentrated, as Baxter and Immuno were the only two companies marketing those products in the United States; and 2) the market for fibrin sealants, a product that controls bleeding in surgical procedures, in which there were no current producers in the United States and Baxter and Immuno were two of only a few companies seeking FDA approval for the products. 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 acquisition would have allowed Baxter to eliminate one of the research tracks and exercise unilateral market power. The order 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 order also required licensure of Baxter's fibrin sealant, and required Baxter to provide the acquirer, Haemacure, with finished product for sale.

J.C. Penney Company/Eckerd Corporation/Rite Aid, 123 F.T.C. 778, 795 (1997) (consent orders) (http://www.ftc.gov/os/caselist/c3721c3722.shtm). In October, 1996, Thrift Drug, a subsidiary of J.C. Penny entered into an agreement to purchase 190 drug stores in North and South Carolina from Rite Aid; in November, 1996, Omega Acquisition Corp., another subsidiary of J.C. Penny, entered into an agreement to purchase Eckerd, which owned 1,724 drug stores in thirteen states including North and South Carolina. The complaint charged that the acquisitions would give J.C. Penny a dominant position in Charlotte, Greensboro, and Raleigh-Durham, North Carolina, and Charleston, South Carolina, and allow J.C. Penny to raise prices for pharmacy services to third-party payers. The order required J.C. Penny to divest 161 drug stores: 34 Thrift drug stores in the Charlotte and Raleigh-Durham areas, 110 Rite Aid drug stores in North Carolina, and 17 Rite Aid drug stores in Charleston, South Carolina. The order barred J.C. Penny from acquiring the 127 stores in North and South Carolina until a divestiture

agreement approved by the Commission was in place, and in addition, allowed the Commission to appoint a trustee to divest the other 63 drug stores acquired from Rite Aid if the divestitures of the 127 stores were not completed on time. The order also required that the stores be divested to a single pharmacy chain to ensure that the buyer could maintain the size and resources necessary to serve as a competitive pharmacy chain in a PBM's pharmacy network.

CVS Corporation/Revco, 124 F.T.C. 161 (1997) (consent order) (http://www.ftc.gov/os/decisions/docs/vol124/FTC_VOLUME_DECISION_124_(JULY_-_DECEMBER_1997)PAGES_126-214.pdf#page=36); Civil Action No. 1:98CV0775 (D.D.C. filed March 26, 1998). The complaint charged that the merger of two large retail drug store chains, CVS and Revco, would give the combined company a dominant position in pharmacy services in Virginia, and in the Binghamton, New York area. According to the complaint, the combined firm would have the ability to increase prices for the sale of retail pharmacy services and restrict services to third-party payers, particularly affecting retail pharmacy networks administered by PBMs which depend on competition among pharmacy chains to keep the cost of pharmacy services competitive. The order required CVS to divest 114 Revco drug stores in Virginia to Eckerd Corporation, and to divest six Revco drug stores in the Binghamton market to Medicine Shoppe. The order allowed the Commission to appoint a trustee who would have the right to divest all 234 Revco drug stores in Virginia and 11 CVS drug stores in the Binghamton market if the required divestitures were not completed three months after the order was finally approved by the Commission. In addition, CVS and Revco signed an asset maintenance agreement requiring them to preserve the viability and competitiveness of the drug stores to be divested. In March 1998, CVS agreed to pay a $600,000 civil penalty for violating the asset maintenance agreement, the violation of which resulted in the inability of Eckerd to offer pharmacy services that were competitive with the services offered by the pharmacies CVS retained. According to the complaint which was filed in U.S. District Court for the District of Columbia, CVS removed the pharmacy computers and all access to Revco's online data systems prior to the divestiture of the Virginia pharmacies to Eckerd, and then refused to provide Eckerd with the patient pharmacy files in a computerized format that could be used by Eckerd's online computer system.

Rite Aid Corporation/Revco D.S., Inc., FTC File No. 961-0020 (preliminary injunction authorized April 17, 1996) (http://www.ftc.gov/news-events/press-releases/1996/04/ftc-will-seek-block-rite-aidrevco-merger). On April 17, 1996, the Commission authorized staff to seek a preliminary injunction to block the acquisition of the Ohio based Revco drug store chain by Rite Aid, which is headquartered in Pennsylvania. The complaint charged that the merger of the two largest retail drug store chains in the country would substantially reduce competition for prescription drugs sold in retail pharmacy outlets in numerous geographic areas, including Ohio, Indiana, Maryland, Pennsylvania, Virginia, West Virginia, North Carolina and New York. A week after the Commission's decision to challenge the transaction, Rite Aid notified the Commission that it had abandoned the transaction.

Rite Aid Corporation/Brooks Pharmacies, FTC File No. 951-0120 (closing letter sent May 31, 1996) (http://www.ftc.gov/opa/1996/06/ram.htm). In September, 1995, Rite Aid entered into an agreement with the Commission under which it was allowed to acquire several Brooks retail

pharmacy stores in Maine from Maxi Drug, Inc. pending completion of the Commission's investigation into possible antitrust violations. As a condition for the Commission agreeing not to challenge the acquisition in federal district court, Rite Aid agreed to maintain the marketability and viability of Rite Aid's and Brooks' pharmacies, and to restore any lost competition in the relevant markets. Rite Aid reached a similar agreement with the Maine Attorney General's Office, which investigated the case jointly with the FTC. The Commission closed its investigation in June, 1996, citing a consent agreement that Rite Aid entered into with the Maine Attorney General requiring Rite Aid to divest pharmacies in three relevant geographic markets in Maine.

IVAX/Zenith Laboratories, 119 F.T.C. 357 (1995) (consent order) (http://www.ftc.gov/os/decisions/docs/vol119/FTC_VOLUME_DECISION_119_(JANUARY_-_JUNE_1995)PAGES_316-412.pdf#page=42). The Commission charged that the merger of IVAX and Zenith would create a monopoly in the market for extended release verapamil, a generic drug used to treat patients with chronic cardiac conditions. IVAX manufactured and sold Verapamil, and Zenith held an exclusive marketing and sales distribution agreement for Verapamil with G.D. Searle. The consent order permitted IVAX to acquire Zenith except for Zenith's rights to market or sell verapamil under Zenith's exclusive distribution agreement with Searle. For ten years, the order also required IVAX to obtain prior Commission approval before acquiring any stock in a company that manufacturers or is an exclusive distributor for another manufacturer for extended-release verapamil. The prior approval requirement also applies to any exclusive agreement IVAX negotiates to distribute another manufacturer's extended-release verapamil.

American Home Products Corporation/American Cyanamid Company, 119 F.T.C. 217 (1995) (consent order) (http://www.ftc.gov/os/decisions/docs/vol119/FTC_VOLUME_DECISION_119_(JANUARY_-_JUNE_1995)PAGES_217-315.pdf). The complaint charged that American Home Products and American Cyanamid competed or potentially competed with each other in three highly concentrated markets for tetanus and diphtheria vaccines, cytokine drugs administered to patients undergoing chemotherapy, and research for a vaccine to treat rotavirus, a diarrheal disease. The consent order required that American Home Products divest its tetanus and diphtheria vaccine business to a Commission approved buyer, and license American Cyanamid's rotavirus research to a Commission-approved licensee. American Home Products licensed the manufacturing rights of two cytokines that were pending FDA approval to Sandoz. American Home Products licensed the manufacturing rights of two cytokines that were pending FDA approval to Sandoz. The order required changing the licensing agreement for cytokines and eliminating reporting arrangements to assure that American Home Products does not obtain competitively-sensitive information.

Rite Aid Corporation/LaVerdiere's Enterprises, Inc., 118 F.T.C. 1206 (1994) (consent order), Civil Action No. 1:98CV0484 (D.D.C. filed February 27, 1998), 125 F.T.C. 846 (1998) (modifying order) (http://www.ftc.gov/os/decisions/docs/vol118/FTC_VOLUME_DECISION_118_(JULY_-_DECEMBER_1994)PAGES_1130-1228.pdf#page=77). The complaint charged that Rite Aid's

acquisition of LaVerdiere would substantially lessen competition and increase the prices for prescription drugs sold in retail pharmacy stores in Bucksport and Lincoln, Maine, and in Berlin, New Hampshire. The order required Rite Aid to divest either its own drug stores or the acquired LaVerdiere drug stores in the three cities to a Commission-approved buyer who would operate the stores in competition with Rite Aid. Rite Aid failed to meet the twelve-month deadline for divestiture, and in February, 1996, the Commission appointed a trustee to divest the drug stores. The trustee found buyers for the Lincoln, Maine store and the Berlin, New Hampshire store, but could not find a buyer for the Bucksport, Maine store. In February, 1998 Rite Aid agreed to pay a $900,000 civil penalty to settle a Commission civil complaint filed in U.S. District Court for the District of Columbia that it failed to comply with the divestiture terms of the 1994 order. Rite Aid then petitioned the Commission to reopen and modify the 1994 order to eliminate the divestiture requirement for the Bucksport, Maine store because neither Rite Aid nor the trustee had been able to find a buyer. The Commission granted the petition in May, 1998, eliminated the divestiture requirement for the Bucksport store, and substituted prior notification and waiting requirements for the prior approval requirement.

TCH Corporation, et al., 118 F.T.C. 368 (1994) (consent order) (http://www.ftc.gov/os/decisions/docs/vol118/FTC_VOLUME_DECISION_118_(JULY_-_DECEMBER_1994)PAGES_340-451.pdf#page=29). The complaint charged that the merger of two drug store chains, TCH and Payless, would violate the antitrust laws, and lead to higher prices and restricted output in six markets in California, Oregon and Washington: Fort Bragg, Bishop, Mt. Shasta, and Taft, California; Florence, Oregon; and Ellensburg, Washington. TCH already owned the Thrifty drug store chain and Bi-Mart, a chain of membership discount stores. The complaint also alleged that the acquisition would eliminate competition between Thrifty or Bi-Mart and Payless, and increase the likelihood of market control or collusion by Thrifty. The order required TCH to divest to Commission-approved buyers, within one year, the pharmacy business in either the Thrifty, Bi-Mart, or Payless drug stores in the six markets. The order also required TCH to maintain the drugs stores until divested as viable and marketable assets.

Revco D.S. Inc./Hook-SupeRx, 118 F.T.C. 1018 (1994) (consent order) (http://www.ftc.gov/os/decisions/docs/vol118/FTC_VOLUME_DECISION_118_(JULY_-_DECEMBER_1994)PAGES_930-1029.pdf#page=89). The complaint charged that the acquisition of the Hook-SupeRx drugstore chain by Revco would substantially reduce competition, raise prices, and reduce service in three markets in Covington, Marion, and Radford, Virginia. The order required Revco to divest either its own pharmacies or the pharmacies acquired from Hook-SupeRx in the three towns within one year, and to maintain the viability of the pharmacies prior to divestiture. The order also provided for the appointment of a trustee if the one year deadline for divestiture was not met. In March 1995, the Commission approved Revco's divestiture of two Hook-SupeRx pharmacies in Radford. The Commission appointed a trustee in February 1996 to divest the pharmacies in Covington and Marion because Revco had failed to meet the divestiture deadline called for in the 1994 order. In November 1996, the Commission approved an application from the trustee to divest the drug stores in Marion and Covington to Horizon Pharmacies Inc.

Dow Chemical Company, et. al., 118 F.T.C. 730 (1994) (consent order) (http://www.ftc.gov/os/decisions/docs/vol118/FTC_VOLUME_DECISION_118_(JULY_-_DECEMBER_1994)PAGES_730-820.pdf). The complaint alleged that the purchase of Rugby Darby Group Companies, Inc. (Rugby) by Marion Merrell Dow, Inc. (MMD) would substantially lessen competition by creating a monopoly in the U.S. market for dicyclomine capsules and tablets, a medication used to treat irritable-bowel syndrome. According to the complaint, MMD and Rugby competed directly and were the only two FDA approved manufacturers of dicyclomine in the U.S. The order required MMD to license dicyclomine formulations and production technology to a third party within12 months, and to contract manufacture dicyclomine for a third party awaiting FDA approval to sell its own dicyclomine. For a period of ten years, the order also required MMD and its parent Dow Chemical to obtain prior approval of the Commission before acquiring any dicyclomine manufacturing, production, or distribution capabilities.

B. Potential Competition Mergers

Watson Pharmaceuticals, Inc./Robin Hood Holdings ("Arrow"), C-4276, FTC File No. 0910116 (consent order issued January 7, 2010) (www.ftc.gov/os/caselist/0910116/index.shtm). The Commission's complaint challenges Watson's proposed $1.75 billion acquisition of Arrow. The complaint charges that the acquisition would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by eliminating significant future competition by reducing the number of potential generic pharmaceutical suppliers in the U.S. markets for generic cabergoline tablets and generic dronabinol capsules. Cabergoline – the generic name of Pfizer's branded drug Dostinex – is a dopamine receptor agonist used to treat Parkinson's Disease and multiple medical problems resulting from excessive production of the hormone prolactin. Arrow is one of only three suppliers of generic cabergoline in the $44.8 million U.S. market. Watson has FDA approval to sell generic cabergoline, and is poised to enter the market within two years. The proposed acquisition, however, would eliminate the likely entry of Watson's competing product. Dronabinol – the generic form of Solvay's Marinol – is used to treat nausea and vomiting caused by cancer therapy, as well as loss of appetite and weight loss in HIV patients. Watson is one of only two suppliers of generic dronabinol in the $74.4 million U.S. market. Arrow's subsidiary, Resolution Chemicals Ltd., is developing a generic dronabinol product, and is one of a limited number of firms capable of developing generic dronabinol and marketing it in a manner that is timely and sufficient to have a competitive impact. The proposed acquisition would eliminate the likely entry of the Arrow/Resolution competing product.

The complaint charges that the proposed acquisition would cause significant competitive harm in these two generic markets. In generic markets, pricing is heavily influenced by the number of competitors in the market. The price of a generic product generally decreases with the entry of the second, third, and even fourth competitor. The proposed acquisition would eliminate a likely future competitor in each of the markets at issue, reduce future competition in those markets between Watson and Arrow, and increase the likelihood that consumers will pay higher prices for these generic products. The complaint states that entry into these generic

markets would not be timely or sufficient to deter or counteract the anticompetitive effects of the proposed acquisition, because of long drug development times, regulatory requirements, and unique conditions within each market that make additional entry unlikely. The consent order requires Watson to divest its generic cabergoline product to Impax Laboratories, Inc. The order also requires Arrow to divest its Resolution subsidiary to a new entity named Reso Holdings, which is owned in part by Resolution's current management. The order also requires Arrow to sell its U.S. marketing rights for generic dronabinol to Impax, which will replicate Arrow's role as the U.S. marketer for that product once Resolution obtains all necessary regulatory approvals. The acquirers of the divested assets must receive prior approval from the Commission, so that the competitive environment that existed in these markets prior to the proposed acquisition will be maintained.

Schering-Plough Corporation/Merck & Co., Inc. (See Section II A for citation and annotation.)

Teva Pharmaceutical Industries Ltd./Barr Pharmaceuticals, Inc. (See Section III A for citation and annotation.)

Sun Pharmaceuticals Industries/Taro Pharmaceutical Industries (See Section III A for citation and annotation.)

Hospira, Inc./Mayne Pharma Limited (See Section III A for citation and annotation.)

Johnson & Johnson/Pfizer (See Section III A for citation and annotation.)

Watson Pharmaceuticals Inc./Andrx Corp. (See Section III A for citation and annotation.)

Barr Pharmaceuticals Inc./Pliva (See Section III A for citation and annotation.)

Allergan Inc./Inamed Corp., C-4156 (consent order issued April 17, 2006) (http://www.ftc.gov/os/caselist/0610031/0610031.htm). The complaint charged that Allergan's acquisition of Inamed would reduce competition and remove a future competitor in the market for botulinum toxin type A products, used for the non-surgical removal of wrinkles. Allergan marketed Botux, the only botulinum toxin approved by the FDA to treat facial wrinkles. Inamed licensed the exclusive rights from Ibsen to develop and distribute Reloxin, and was planning to enter the market with Reloxin, currently in Phase III clinical development. The order requires that Allergan divest the development and distribution rights, including the ongoing clinical trials, for Reloxin to Ipsen, ensure that confidential business information relating to Reloxin will not be obtained by Allergan, and provides that Ipsen will be able to enter into employment contracts with key individuals who have experience relating to Reloxin.

Teva Pharmaceutical Industries/IVAX Corporation (See Section III A for citation and annotation.)

Cephalon, Inc./Cima Labs Inc., 138 F.T.C. 583 (2004) (consent order) (http://www.ftc.gov/os/decisions/docs/Volume138.pdf#page=588). The complaint charged that Cephalon's acquisition of Cima Labs would lessen potential competition and create a monopoly in the market for prescription drugs for the treatment of breakthrough cancer pain (BTCP). Cephalon marketed Actiq (fentanyl), the only FDA approved drug for the treatment of BTCP, and was in the process of developing a sugar free formulation for launch in 2005. Cima Labs was in Phase III clinical trials of Ora Vescent fentanyl, a fast-dissolving, sugar-free fentanyl product, and the firm best positioned to enter the BTCP drug market. The complaint also charged that the acquisition could delay or end the launch of Ora Vescent fentanyl, eliminate the price competition resulting from Cima Labs' entry into the market, and delay entry of generic Actiq into the BTCP drug market. The order requires Cephalon to grant a license and transfer all of the technological knowledge for Actiq to Barr Laboratories, a generic drug manufacturer, in order that Barr can market a generic equivalent of Actiq that will be launched as soon as the FDA approves Cima Labs' Ora Vescent fentanyl. The order also contains provisions to ensure that Barr is able to compete successfully in the BTCP drug market and that Cephalon does not delay the development and launch of Ora Vescent fentanyl.

Pfizer Inc./Pharmacia Corporation (See Section III A for citation and annotation.)

Baxter International Inc./Wyeth Corporation (See Section III A for citation and annotation.)

Amgen Inc./Immunex Corporation (See Section III A for citation and annotation.)

Cytyc Corp./Digene Corp., FTC File No.0210098 (preliminary injunction authorized June 24, 2002) (http://www.ftc.gov/news-events/press-releases/2002/06/ftc-seeks-block-cytyc-corps-acquisition-digene-corp . The Commission authorized staff to seek a preliminary injunction that would block the proposed merger of two corporations that manufacture and sell tests used in screening for cervical cancer. Cytyc accounted for 93% of the US market for liquid-based Pap tests used in primary screening for cervical cancer. Only one other company, Tripath Imaging, marketed an FDA-approved liquid-based Pap test, and a few other companies may have entered the market in the future. Digene was the only FDA approved supplier of a DNA-based test for the human papillomavirus (HPV) which is thought to be the cause of cervical cancer. Digene's HPV test was used as a back-up test for equivocal Pap tests but was likely to become a primary screening test, first in conjunction with a liquid Pap test, and then as a stand-alone test. Cytyc was the only company that had FDA approval to market the use of the HPV test from its liquid Pap test samples. If filed in court, the Commission's complaint would have alleged that as a result of the acquisition, Cytyc would be in a position to eliminate Tripath as a competitor by limiting access to Digene's HPV test, and to prevent the entry of other companies that had plans to sell liquid Pap tests in the future. The Commission also cited concerns that the acquisition would eliminate future competition between Cytyc's liquid Pap test and Digene's HPV test as a primary screening test. Within a week after the Commission's decision to challenge the transaction, Digene terminated its acquisition agreement with Cytyc.

Glaxo Wellcome PLC/SmithKline Beecham PLC (See Section III A for citation and annotation.)

Hoechst AG/Rhone-Poulenc, C-3919 (consent order issued January 18, 2000) (http://www.ftc.gov/enforcement/cases-proceedings/9910071/hoechst-ag-rhone-poulenc-sa-be-renamed-aventis-sa). The complaint charged that Hoechst's acquisition of Rhone-Poulenc would harm competition in the market for direct thrombin inhibitors, which are drugs used in the treatment of blood clotting diseases. Sales of direct thrombin inhibitors total about $15 million in the U.S. market. Hoechst sold Refludan, the only direct thrombin inhibitor currently sold in the U.S. market. Rhone-Poulenc was in the final stages of developing its direct thrombin inhibitor, Revasc, which it licensed from Novartis in 1998. According to the complaint, direct thrombin inhibitors are more effective and safer than other available alternatives for treating blood clotting diseases, and Hoechst and Rhone-Poulenc were each other's closest competitors. The complaint charged that the merger eliminated direct competition between Hoechst and Rhone-Poulenc, and in addition, reduced potential competition and innovation competition among researchers and developers of direct thrombin inhibitors. The order required Hoechst to transfer all of Rhone-Poulenc's rights for Revasc to Novartis or some other third party, and to enter into a short term service agreement with the acquirer of Revasc in order to ensure the continued performance of development work on Revasc.

Zeneca Group PLC, 127 F.T.C. 874 (1999) (consent order) (*not currently available online at FTC.gov*). Zeneca's proposed acquisition of Astra raised antitrust concerns based upon potential competition. Zeneca 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, and for certain procedures 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.

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 three percent investment interest in Chiroscience.

Hoechst AG, 120 F.T.C. 1010 (1995) (consent order) (http://www.ftc.gov/os/decisions/docs/vol120/FTC_VOLUME_DECISION_120_(JULY_-_DECEMBER_1995)PAGES_1003_-_1077.pdf#page=8). The complaint alleged that potential

competition would be harmed in four markets if Hoechst, a German pharmaceutical company, acquired Marion Merrill Dow in a $7.1 billion dollar 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 relevant markets all featured current production by one of the merging firms and the potential for the other firm to enter the market with a new product: 1) The largest market was the $1 billion once-a-day diltiazem 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. Although Hoechst returned the rights to Tiazac to Biovail before the merger agreement was finalized, the order also required Hoechst to provide Biovail with a letter of access to toxicology data necessary to secure FDA approval, to return to Biovail and refrain from using any confidential information, and to end and refrain from litigations or citizen petitions regarding Tiazac; 2) Hoechst marketed Trental, 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 rights to Beraprost, one of the few drugs in development for this condition before the merger. The order required Hoechst to divest either Trental or Beraprost; 3) MMD marketed Pentasa, 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. Hoechst was required to divest one of the two drugs; 4) 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 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; and to prevent the deterioration of the assets involved, maintain its research and development efforts at pre-merger planned levels pending divestiture, and provide technical assistance and advice to the purchasers in obtaining FDA approval.

American Home Products Corporation/American Cyanamid Company (See Section III A for citation and annotation.)

C. Innovation Market Mergers

Teva Pharmaceutical Industries Ltd./Barr Pharmaceuticals, Inc. (See Section III A for citation and annotation.)

Pfizer Inc./Warner-Lambert Company (See Section III A for citation and annotation.)

Baxter International, Inc. (See Section III A for citation and annotation.)

Ciba-Geigy, Ltd., 123 F.T.C. 842 (1997) (consent order) (http://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-123). The complaint alleged that the merger of Ciba-Geigy and Sandoz would result in an anticompetitive impact on the innovation of gene 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 in order to have any hope of commercializing their own research efforts. 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. 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 complaint 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 complaint 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 complaint 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 order 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. Further, the merged company could not acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy.

The Upjohn Co., 121 F.T.C. 44 (1996) (consent order) (http://www.ftc.gov/os/decisions/docs/vol121/FTC_VOLUME_DECISION_121_(JANUARY_-_JUNE_1996)PAGES_1-97.pdf#page=44). The complaint 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. 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 complaint 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 order required the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.

Glaxo PLC, 119 F.T.C. 815 (1995) (http://www.ftc.gov/os/decisions/docs/vol119/FTC_VOLUME_DECISION_119_(JANUARY_-

_JUNE_1995)PAGES_724-829.pdf#page=92). In Glaxo, the complaint 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 complaint alleged that the acquisition would eliminate actual competition between the two companies in researching and developing migraine remedies. The complaint 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. The order 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.

D. Vertical Mergers

Fresenius Medical Care/Daiichi Sankyo, C-4236 (consent order issued October 20, 2008) (http://www.ftc.gov/os/caselist/0810146/index.shtm). The complaint alleged that Fresenius' acquisition of an exclusive sublicense to manufacture and supply the intravenous iron drug Venofer to dialysis clinics would allow Fresenius, the largest provider of dialysis services and products, to increase Medicare reimbursement payments for Venofer. Venofer is used to treat iron deficiency anemia in patients undergoing chronic hemodialysis and is reimbursed by Medicare under the Medicare Part B end-stage renal disease program based on the manufacturer's average sales price ("ASP") plus six percent. Drug manufacturers are required to submit their ASP to the Center for Medicare & Medicaid Services ("CMS") each calendar quarter and that information is used to calculate the CMS reimbursement rate. According to the complaint, the acquisition would give Fresenius the ability and incentive to report higher prices for Venofer used in its own clinics to CMS thereby increasing Fresenius' ASP. Under the order, Fresenius will be restricted from reporting an intra-company transfer price higher than the level set in the order which is derived from current market prices. In addition, the order provides that if a generic Venofer product receives final approval by the FDA, Fresenius will be required to report its intra-company transfer price at the lowest of either the level set forth in the order or the lowest price at which Fresenius sells Venofer to any customer until December 31, 2011. On January 1, 2012, CMS will implement a new reimbursement methodology based on a new bundled pricing system which will eliminate the concerns raised by the transaction.

Merck & Co., Inc., 127 F.T.C. 156 (1999) (consent order) (*not currently available online at FTC.gov*). 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 order 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.

Eli Lilly/PCS 120 F.T.C. 243 (1985) (consent order) (http://www.ftc.gov/os/decisions/docs/vol120/FTC_VOLUME_DECISION_120_(JULY_-_DECEMBER_1995)PAGES_206_-_311.pdf#page=38); 127 F.T.C. 577 (1999) (set aside order). The complaint alleged that Lilly's acquisition of PCS, a pharmacy benefits manager ("PBM"), from McKesson Corp. would allow Lilly to favor its own drugs on PCS's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order 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 order was set aside in 1999 because Lilly sold PCS to Rite Aid Corp.

IV. INDUSTRY GUIDANCE STATEMENTS

A. Advisory Opinions

Under the statements, the Commission has committed to responding within 90 days to requests for advice from health care plans or providers about matters addressed by the "safety zones" or the non-merger policy statements; and within 120 days to requests for advice regarding multiprovider networks and other non-merger health care matters. The response period will commence once all necessary information has been received by the Commission.

Information regarding advisory opinions is set forth in the *Topic And Yearly Indices of Health Care Advisory Opinions By Commission And By Staff*. The index and the text of the advisory opinions are available at the FTC's web site at http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

B. Citizen Petition to the Food and Drug Administration

The Bureau of Competition and the Policy Planning Staff of the Federal Trade Commission submitted a Citizen Petition to the Commissioner of Food and Drugs on May 16, 2001, in which it requested guidance on the FTC staff's interpretation of certain FDA regulations related to patent listings in the Orange Book. The petition sought the FDA's views on the two prong criteria that a patent must meet under 21 C.F.R. § 314.53 (b) before it can be listed in the Orange Book. The petition also asked for guidance on other patent listing issues, including whether an NDA holder can list a patent for an unapproved aspect of an approved drug, or a chemical compound not approved for use as the drug substance in an approved drug product, and the meaning of the term "drug product" as it relates to infringement analysis under the regulation. FDA never formally responded to our citizen's petition, but instead issued proposed regulations on October 24, 2002, to modify in part its regulations concerning Orange Book listings. Staff submitted comments to the proposed regulations on December 23, 2002. FDA's proposed regulations remain pending.

V. AMICUS BRIEFS

Brief Amicus Curiae of Federal Trade Commission In Support of Rehearing *En Banc*, Arkansas Carpenters Health and Welfare Fund v. Bayer AG, Bayer Corp. (In Re Ciprofloxacin Hydrochloride Antitrust Litigation), Docket No.'s 05-2851-cv (L) and 05-2852-cv (CON) (2nd Cir.) (May 20, 2010) (https://www.ftc.gov/policy/advocacy/amicus-briefs/2010/05/arkansas-carpenters-health-welfare-fund-et-al-v-bayer-ag-et-al); **Brief of Amicus Curiae Federal Trade Commission, In Support of Appellants and Urging Reversal, In re Ciprofloxacin Hydrochloride Antitrust Litigation**, No. 2008-1097 (Fed. Cir.) (January 25, 2008) (http://www.ftc.gov/os/2008/01/080129cipro.pdf). The case, filed by direct and indirect purchasers of the wide-spectrum antibiotic drug ciprofloxacin hydrochloride ("Cipro"), involves agreements between defendants Bayer AG and its U.S. subsidiary Bayer Corporation – manufacturer of Cipro and assignee of U.S. Patent No. 4,670,444 which claims the active ingredient in Cipro – and generic manufacturers Barr Laboratories, Inc., The Rugby Group, Inc., Hoechst Marion Roussel, Inc., and Watson Pharmaceuticals, Inc. Under the terms of those agreements (executed in January 1997), Bayer paid the generic companies approximately $398 million in exchange for their agreements not to manufacture any form of Cipro and for Barr's agreement to terminate its challenge to Bayer's patent by converting its Abbreviated New Drug Application for a generic form of Cipro to permit Barr to market its generic drug only upon expiration of the '444 patent in December 2003. The Commission urged the Court to reverse the District Court's decision and argues that the district court's ruling is not compelled by the patent laws, and it conflicts with fundamental antitrust principles.

In April 2010, a three-judge panel of the Court of Appeals for the Second Circuit affirmed the district court's summary judgment for the defendants, holding that Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2nd Cir. 2005), was dispositive. See Docket No.'s 05-2851-cv (L) and 05-2852-cv (CON) (2nd Cir. April 29, 2010) (https://www.ftc.gov/news-events/press-releases/2010/04/statement-ftc-chairman-jon-leibowitz-regarding-todays-decision-us). However, "because of the 'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits," the court of appeals' opinion invited the plaintiffs-appellants to petition for rehearing *en banc*, which they did. On May 20, 2010, the Commission filed a brief, as *amicus curiae*, urging the Second Circuit to grant a rehearing *en banc*. On September 7, 2010, the Second Circuit (over one written dissenting opinion) denied the petition for rehearing *en banc*.

Brief for the United States and Federal Trade Commission as Amici Curiae Supporting Plaintiffs-Appellants, **In re DDAVP Direct Purchaser Antitrust Litigation**, No. 06-5525 (2nd Cir.) (May 25, 2007) (http://www.ftc.gov/os/2007/05/DDAVPCommission-DoJBrief.pdf). The plaintiffs, direct purchasers of the branded drug DDAVP, brought a class action under Section 4 of the Clayton Act, alleging that defendants Ferring B.V. and Ferring Pharmaceuticals, Inc., who owned the patent for desmopressin acetate -- the active ingredient in DDAVP, and Aventis Pharmaceuticals, Inc., the patent's exclusive licensee in the United States, violated Section 2 of the Sherman Act, by maintaining and enforcing a patent procured by intentional

fraud on the Patent and Trademark Office. The plaintiffs charged that defendants prevented and delayed lower-priced generic equivalents of DDAVP from entering the market. In their brief, the Department of Justice and the Federal Trade Commission urged the court of appeals to reverse the district court's holding that plaintiffs lacked antitrust standing as direct purchasers to bring monopolization claims against the defendants arising out of the manufacturers' maintenance and enforcement of a patent allegedly procured through intentional fraud on the Patent and Trademark Office.

Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants' Petition for Panel Rehearing and Rehearing En Banc, **In re Tamoxifen Citrate Antitrust Litigation**, Case No. 03-7641 (2nd Cir.), filed November 30, 2005 (http://www.ftc.gov/os/2005/12/051202amicustamoxifen.pdf). The Appeals Court upheld a district court's dismissal of an antitrust challenge to a patent litigation settlement between AstraZeneca, the manufacturer of the cancer treatment drug, tamoxifen citrate, and Barr Laboratories. The Commission's brief argued that the Appeals Court panel did not properly consider the Hatch Waxman Act which encourages challenges to patents in order to facilitate the early entry of generic drugs into the market. The Commission argued that the Appeals Court decision, if not corrected, would permit the holder of a challenged drug patent to forestall competition by paying a generic rival to stay out of the market even if its patent claims are weak. The Commission also argued that consumers have benefitted from the large savings that have resulted from successful challenges to listed patents.

Brief of Amicus Curiae Federal Trade Commission Supporting Appellant's Combined Petition for Rehearing and Rehearing En Banc, Case No. 03-CV-10167 (Fed Cir.), filed 2/11/05 (http://www.ftc.gov/os/caselist/tevapharm/tevapharm.htm); **Brief of Amicus Curiae Federal Trade Commission Supporting Appellant and Urging Reversal** in **Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.**, Case No. 04-1186 (Fed. Cir.), filed March 31, 2004 (https://www.ftc.gov/policy/advocacy/amicus-briefs/2004/03/teva-pharmaceuticals-usa-inc-v-pfizer-inc). Teva sought a declaratory judgment that its generic version of Pfizer's sertraline hydrochloride drug would not infringe a patent held by Pfizer (or that the patent was invalid). The district court dismissed Teva's complaint for lack of subject matter jurisdiction. The Commission's brief explains that declaratory actions by generic companies (such as Teva) play a vital role in the Hatch-Waxman regime by providing these applicants with the opportunity to eliminate bottlenecks that can delay them from obtaining FDA approval to market their product. The brief argues that the district court applied the wrong test to assess jurisdiction in the Hatch-Waxman cases brought by a "second" generic applicant, such as Teva. It argues that the court failed to take account of the fact that, unless Teva can obtain a court decision regarding Pfizer's patent, the FDA cannot give Teva approval to market its generic drug until 180 days after the first generic applicant (Ivax Pharmaceuticals) enters the market with its version. The brief also explained that the district court's holding will leave subsequent generic applicants (such as Teva) powerless to prevent brand-name manufacturers and first generic applicants from greatly delaying other generic manufacturers from entering the market. On January 21, 2005, the Court of Appeals for the Federal Circuit affirmed the judgment of the district court. On February 11, 2005, the Commission filed a second amicus brief in support of Teva's combined petition for

rehearing and rehearing en banc, arguing that the district court had not applied the proper standard in evaluating whether there was an actual controversy between Teva and Pfizer.

Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpham's Cross Motion for Entry of An Amended Order in **SmithKline Beecham Corporation v. Apotex Corporation**, Case No. 99-CV-4304 (E.D. Pa., January 29, 2003) (http://www.ftc.gov/ogc/briefs/smithklineamicus.pdf). Smithkline Beecham (now GlaxoSmithKline) sued Apotex, a generic drug manufacturer, for infringing two patents on its antidepressant drug Paxil. After the district court ruled the Glaxo patents invalid, Apotex filed a motion to have the two patent listings removed from the Orange Book. In response to this motion, the Commission filed an amicus brief arguing that improper listings in the Orange Book effect competition and harm consumers. The Commission detailed the anticompetitive effects resulting from improper listings, including additional 30-month stays of FDA approval, that ultimately delay the entry of generic drugs. The Commission also argued that consumers benefit from the large savings that result from the competition provided by generic drugs, an estimated $30 million dollars a month in the case of a generic Paxil. The Commission argued that a de-listing remedy is consistent with the Court's judgment of invalidity, because it would prevent the branded manufacturer from benefitting from the 30-month stay of FDA approval even after a judgment of invalidity.

Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss in In re: Buspirone Patent, Antitrust Litigation, 185 F. Supp. 2d 363 (SD. NY. 2002) (http://www.ftc.gov/ogc/briefs/buspirone.pdf). The In re: Buspirone Patent and Antitrust Litigation involves claims by generic drug manufacturers that Bristol-Myers-Squibb, manufacturer of the brand drug BuSpar, attempted to delay generic competition to BuSpar, in violation of Section 2 of the Sherman Act, when it filed misrepresentative claims to the FDA concerning the listing of a newly issued patent in the Orange Book. BMS filed a motion to dismiss the case on the grounds that the listing is valid petitioning to a government agency and therefore immune from the antitrust laws under *Noerr*. In its amicus brief, the Commission argued that Orange Book filings are not immune from Sherman Act liability under *Noerr* because: 1) they are ministerial filings and not legitimate petitions intended to influence governmental decision-making; 2) they do not constitute adversarial pre-litigation threat letters incidental to litigation; and 3) they are not necessary for patent infringement litigation. The Commission also argued that even if the Orange Book listings constitute "petitioning" under *Noerr*, the misrepresentation and sham exceptions may deprive BMS of *Noerr* immunity. The court ruled that the listing of the buspirone patent in the Orange Book was not valid petitioning of a government agency and therefore not protected under *Noerr;* in addition, according to the court, the plaintiffs had shown that there was reason to warrant an exception to *Noerr* immunity because BMS had obtained the patent fraudulently and attempted to maintain a monopoly by bringing the patent litigation.

Brief of the Federal Trade Commission as Amicus Curiae in American Bioscience, Inc. v. Bristol-Myers Squibb Co., No. CV-00-08577 WMB (AJWx) (C.D. Cal., September 1, 2000) (https://www.ftc.gov/policy/advocacy/amicus-briefs/2000/09/american-bioscience-v-bristol-myers). American Bioscience, Inc. (ABI) sued Bristol-Myers Squibb, the maker of Taxol, a drug

used to treat cancer, to force it to list a patent on the FDA Orange Book, and obtained an unopposed temporary restraining order (TRO). As part of a proposed settlement between ABI and Bristol, the parties agreed that (1) the court would enter a finding that ABI's patent should be listed in the Orange Book, and (2) Bristol would maintain the listing of the patent in the Orange Book. In its amicus brief, the Commission asked the judge to consider the anticompetitive ramifications of the proposed settlement. First, another court might find any judicial finding that the patent met the statutory requirements for listing on the Orange Book persuasive, or even conclusive, thus hindering a generic company's attempt to challenge the listing. Second, the order to maintain the listing would conflict with any later court order requiring Bristol to delist the patent, and resolving the conflicting court orders could further forestall generic entry. The brief also announced the Commission's investigation of ABI and Bristol, and asked the court to consider its pendency when deciding on the proposed settlement. The court ultimately determined that ABI could not maintain a private action under the Food, Drug, and Cosmetics Act, dissolved the TRO, and ordered Bristol to delist the ABI patent.

VI. INDICES

A. Table of Cases

B. Table of Briefs