



# **OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION**

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**June 2025**

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# FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION<sup>1</sup>

## 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 Sherman Act and the Clayton Act.

When litigation becomes necessary, the FTC may conduct an 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 under Section 13(b) of the FTC Act 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 40 lawyers and investigators who work exclusively on health care antitrust matters, including non-merger matters involving the pharmaceutical industry. The Mergers I Division investigates mergers involving pharmaceutical products. FTC actions involving pharmaceutical products and distribution<sup>2</sup> are summarized below.<sup>3</sup> The summaries are intended to provide a brief overview of FTC enforcement actions. They do not reflect all subsequent actions taken by the Commission or the parties. The Commission and its staff have also

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<sup>1</sup> 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 IV describes FTC enforcement involving mergers in the pharmaceutical industry, which are primarily conducted by the Mergers I Division of the Bureau of Competition.

<sup>2</sup> Actions involving health care services and products are contained in a separate document, *Overview of FTC Actions in Health Care Services and Products*, available on the FTC's website at <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

<sup>3</sup> Commission complaints and orders issued since March 1996 are available at the FTC's website at <http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care> (under the "Cases" drop down menu).

responded to numerous requests for guidance from health care industry participants through, among other things, the advisory opinion letter process.<sup>4</sup>

For further information about matters handled by the FTC's Health Care Division, or to lodge complaints about suspected antitrust violations, please write, call, e-mail,<sup>5</sup> or fax this office as follows:

Mailing Address: Health Care Division  
Bureau of Competition  
Federal Trade Commission  
Org. 1035, Mail Stop CC- 6315  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Telephone Number: (202)-326-3759, (202)-326-3670, or (202)-326-2018  
E-Mail: [antitrust@ftc.gov](mailto:antitrust@ftc.gov)  
Fax Number: (202)-326-3384

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

Mailing Address: Mergers I Division  
Bureau of Competition  
Federal Trade Commission  
Org. 1037, Mail Stop CC-6315  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Telephone Number: (202)-326-3106, (202)-326-3506, or (202)-326-2118  
E-Mail: [antitrust@ftc.gov](mailto:antitrust@ftc.gov)  
Fax Number: (202)-326-2655

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<sup>4</sup> 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 on the FTC's website at <http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

<sup>5</sup> Note that e-mail is not secure. Confidential information should be marked "Confidential" and sent via regular mail. To learn how we may use the information you provide, please read our Privacy Policy.

## II. CONDUCT INVOLVING PHARMACEUTICAL PRODUCTS

### A. Monopolization

**Federal Trade Commission, et al. v. Vyera Pharmaceuticals, LLC, et al.**, No. 20-cv-00706, FTC File No. 161-0001 (complaint issued January 27, 2020; amended complaint filed on April 14, 2020; stipulated order for permanent injunction issued December 7, 2021; permanent injunction affirmed January 23, 2024) (<https://www.ftc.gov/news-events/news/press-releases/2024/01/statement-second-circuit-order-upholding-pharma-bro-martin-shkreli-lifetime-ban>). On January 27, 2020, the FTC filed a complaint jointly with the State of New York alleging an elaborate anticompetitive scheme by Vyera Pharmaceuticals, LLC, its parent company Phoenixus AG, its founder Martin Shkreli, and its former CEO Kevin Mulleady to preserve a monopoly for the life-saving drug Daraprim. On April 14, 2020, the FTC and New York filed an amended complaint adding six additional state plaintiffs—California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

Daraprim is the gold standard treatment for toxoplasmosis, a rare parasitic infection that is potentially fatal in immunocompromised patients. When Vyera acquired Daraprim, the drug had been an affordable, life-saving treatment for more than 60 years. Vyera immediately raised the list price by more than 4,000%. The complaint alleged that, to protect the price increase, Defendants entered into a web of restrictive agreements to prevent or at least delay generic competition, including: (i) distribution agreements to prevent potential generic competitors' access to brand samples necessary for FDA-mandated bioequivalence testing; (ii) exclusivity agreements with the most viable manufacturers of pyrimethamine to block access to the active pharmaceutical ingredient in Daraprim; and (iii) "data-blocking" agreements with key distributors to prevent them from selling their Daraprim sales and distribution data to third-party data reporting companies to mask the true size of the Daraprim market opportunity.

On December 7, 2021, the [Federal Trade Commission](#) and its [state co-plaintiffs](#) settled their claims against Vyera, Phoenixus, and Mulleady. The settlement requires the corporate defendants to pay up to \$40 million in equitable monetary relief, with \$10 million guaranteed upfront, to make Daraprim available to any potential generic competitor at list price, and to provide prior notification of any planned pharmaceutical transaction valued at \$25 million or more. For 10 years, Mulleady, Vyera, and Phoenixus are prohibited from engaging in any conduct similar to that alleged in this case. With two narrow exceptions, Mulleady is also banned from the pharmaceutical industry for seven years, and subject to a \$250,000 suspended judgment if he violates the terms of the order.

Judge Denise Cote of the U.S. District Court for the Southern District of New York held a bench trial in the case against Shkreli from December 14 to December 22, 2022. On January 14, 2023, the Court held Shkreli liable for the federal and state antitrust claims brought against him. The Court banned Shkreli from the pharmaceutical industry for life and ordered him to disgorge \$64.6 million in ill-gotten gains. On January 23, 2024, the U.S. Court of Appeals for the Second Circuit affirmed the district court's judgment.

**Impax Laboratories, Inc.**, D-9373, FTC File No. 1410004 (complaint filed January 19, 2017; initial decision May 18, 2018; Commission opinion and final order issued March 28, 2019;

affirmed by U.S. Court of Appeals for the Fifth Circuit April 13, 2021) (<https://www.ftc.gov/news-events/press-releases/2021/04/us-court-appeals-fifth-circuit-upholds-ftcs-opinion-against>). The complaint alleged that Impax had entered into an anticompetitive reverse-payment agreement with Endo Pharmaceuticals Inc. in June 2010 to eliminate the risk of generic competition to Endo's Opana ER, an extended-release opioid indicated for the relief of moderate to severe pain. Under the agreement, Impax agreed to forgo entering the market with its lower-cost generic version of Opana ER for 2.5 years until January 2013. In exchange, Endo agreed that it would refrain from offering an authorized generic Opana ER product during Impax's initial 180 days of marketing its own generic. If market conditions were to change to devalue this no-AG commitment, Endo further agreed to pay Impax a cash amount based on Impax's expected profits for that six-month period of generic exclusivity. Endo also agreed to pay Impax up to \$40 million for a purportedly independent development and co-promotion deal.

The case went to trial on October 24, 2017, with Chief Administrative Law Judge D. Michael Chappell presiding. On May 18, 2018, Judge Chappell issued the initial decision. Judge Chappell found that Impax accepted a large reverse payment from Endo, but that the agreement was justified.

On March 28, 2019, the Commission unanimously reversed the initial decision. The Commission found that Complaint Counsel established a *prima facie* case because (1) Endo possessed market power in the market for branded and generic oxymorphone ER; and (2) Impax received a large and unjustified payment. The Commission further determined that Impax failed to show a cognizable procompetitive rationale for its reverse payment, because it did not prove that the procompetitive benefits it identified were related to the restraint at issue. The Commission found, in the alternative, that a settlement agreement including the allegedly procompetitive terms without the large, unjustified payment provided a viable less restrictive option. Impax appealed. On April 13, 2021, the Fifth Circuit upheld the Commission's decision.

The Commission's final order bars Impax from entering into any type of reverse payment that defers or restricts generic entry, including no-Authorized Generic commitments, as well as certain business transactions entered with the branded pharmaceutical manufacturer within 45 days of a patent settlement.

**Federal Trade Commission v. Reckitt Benckiser Group plc, and Federal Trade Commission v. Indivior, Inc.**, FTC File No. 1310036 (complaint against Reckitt filed July 11, 2019; stipulated order for permanent injunction and equitable monetary relief entered on July 12, 2019; Dkt. 1:19-cv-00028 (W.D. Va.); complaint against Indivior filed July 24, 2020; stipulated order for permanent injunction and equitable monetary relief entered on November 20, 2020; Dkt. 1:20-cv-00036 (W.D. Va.)) (<https://www.ftc.gov/news-events/press-releases/2020/07/indivior-inc-pay-10-million-consumers-settling-ftc-charges>). According to the complaints, Reckitt Benckiser Group (Reckitt) and its former subsidiary, Indivior, Inc., which produced and sold the opioid addiction treatment Suboxone, violated the antitrust laws through a deceptive scheme to thwart lower-priced generic competition to Suboxone. The complaints charged that before generic versions of Suboxone tablets became available, Reckitt Indivior developed a dissolvable oral film version of Suboxone and worked to shift prescriptions to this patent-protected film. Worried that doctors and patients would not want to switch to Suboxone

Film, Reckitt and Indivior allegedly employed a “product hopping” scheme where the companies falsely represented that the film version of Suboxone was safer than Suboxone tablets because children are less likely to be accidentally exposed to the film product. The complaints further charge that to buy more time to move patients to the film version of Suboxone, Reckitt, through Indivior, filed a citizen petition with the FDA reciting the same unsupported safety claims and requesting that the agency reject any generic tablet application, effectively delaying the approval of generic competitors. In 2014, the FTC’s non-public investigation of this conduct was largely put on hold due to a parallel federal criminal investigation for related conduct. The criminal investigation ultimately resulted in a \$1.4 billion settlement and non-prosecution agreement with Reckitt, guilty pleas from two former Indivior executives and an Indivior subsidiary (Indivior Solutions, Inc.), and a civil settlement with Indivior. (<https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million>)

In its civil settlement with the FTC, Reckitt agreed to a [stipulated order for equitable monetary relief and a permanent injunction, which](#) bars Reckitt from similar future misconduct. If Reckitt introduces a reformulated version of an existing product, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded drug, the order requires Reckitt to leave the original product on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the drug they prefer. The order also requires that if Reckitt files a citizen petition, the company must simultaneously submit any data or information underlying that petition to the FDA and FTC. As part of the order, Reckitt agreed to pay \$50 million in equitable monetary relief.

In a follow-up settlement, Indivior agreed to pay \$10 million to settle FTC charges regarding the same conduct. Indivior also agreed to a similar [proposed stipulated order for equitable monetary relief and a permanent injunction](#), which bars it from similar future misconduct. The \$10 million from this settlement will be combined with the \$50 million from the Reckitt settlement into a fund that will provide payments to people who purchased Suboxone Oral Film.

**Federal Trade Commission v. Shire ViroPharma Inc.**, Civil Action No. 1:17-cv-00131-RGA (D. Del.), FTC File No. 1210062 (complaint filed February 7, 2017; complaint dismissed March 20, 2018) (<https://www.ftc.gov/enforcement/cases-proceedings/121-0062/shire-viopharma>). The complaint alleged that Shire ViroPharma Inc. (“ViroPharma”) abused government processes to delay generic competition to its branded Vancocin Capsules. Vancocin Capsules are used to treat a potentially life-threatening gastrointestinal infection. Specifically, the complaint alleged that ViroPharma waged a campaign of serial, repetitive, and unsupported filings with the U.S. Food and Drug Administration (“FDA”) and courts to delay the FDA’s approval of generic Vancocin Capsules and competition to its drug product. ViroPharma submitted 43 filings with the FDA and filed three lawsuits against the FDA between 2006 and 2012. According to the complaint, ViroPharma’s filings lacked supporting clinical data, which ViroPharma understood it needed to have any chance of persuading the FDA for approval. ViroPharma also allegedly knew that its petitioning was obstructing and delaying the FDA’s approval of generic Vancocin Capsules. The Commission sought a court order permanently prohibiting ViroPharma from submitting



repetitive and baseless filings with the FDA and the courts, and from similar and related conduct as well as any other necessary equitable relief, including restitution and disgorgement.

On March 20, 2018, the district court dismissed the FTC's complaint for failure to sufficiently allege that ViroPharma "is violating or about to violate" the law under section 13(b) of the FTC Act. The FTC appealed the ruling to the Third Circuit on June 19, 2018. On February 25, 2019, the Third Circuit affirmed the district court's judgment.

**Federal Trade Commission, et al. v. Mallinckrodt ARD Inc., et al.**, Civil Action No. 1:17-cv-00120 (D.D.C.), FTC File No. 1310172 (stipulated order for permanent injunction and equitable monetary relief approved January 30, 2017) (<https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals>).

The complaint alleged that, while benefitting from an existing monopoly over the only U.S. adrenocorticotrophic hormone (ACTH) drug, H.P. Acthar Gel, Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., illegally acquired the U.S. rights to develop a competing drug, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH drug, preserving Mallinckrodt's monopoly and allowing it to maintain extremely high prices for Acthar. Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, and a drug of last resort to treat several other serious medical conditions – including nephrotic syndrome, flare-ups of multiple sclerosis, and rheumatoid disorders. Since 2001, Mallinckrodt has raised the price of Acthar from \$40 per vial to over \$34,000 per vial – an 85,000% increase.

Under the stipulated court order, Mallinckrodt must make a \$100 million monetary payment to the Commission. Mallinckrodt must also grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.

**Federal Trade Commission v. Allergan PLC, et al.**, Case No. 17-cv-00312 (N.D. Cal.), FTC File No. 1410004 (complaint filed January 23, 2017) (stipulated order for permanent injunction covering Endo defendants entered February 2, 2017; global settlement entered with Teva February 19, 2019) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0004/allergan-plc-watson-laboratories-inc-et-al>). The complaint alleged that the defendants had entered into a reverse-payment agreement to eliminate the risk of lower-cost generic competition to Endo Pharmaceutical Inc.'s Lidoderm, a topical patch used to relieve pain associated with a complication of shingles known as post-herpetic neuralgia. Under the agreement, Watson Laboratories, Inc. agreed to forgo entry with a lower-cost generic version of Lidoderm for more than a year. In return, Endo agreed to refrain from competing with an Authorized Generic for up to the first 7 ½ months of Watson's generic sales. This no-Authorized Generic commitment was worth hundreds of millions of dollars to Watson. Second, Endo agreed to provide Watson with branded Lidoderm patches valued at \$96-240 million at no cost. The complaint also named Allergan plc and Allergan Finance LLC, Watson's parent at the time of the settlement that led the negotiations of the settlement and directly benefitted from the reverse payments.

On February 2, 2017, the Court accepted an agreement between the Commission and Endo effectively bringing litigation between the two parties to an end. Under the agreement, Endo and its subsidiaries are prohibited from entering into the type of anticompetitive agreements that the

Commission had alleged that it had previously used to prevent generic entry. The order allows Endo to enter supply agreements in connection with patent settlements if the agreements comply with certain requirements. The order authorizes the Commission to appoint a monitor with the authority to evaluate whether these supply agreements comply with the order's requirements.

On February 19, 2019, the Commission reached a global settlement with Watson's parent company, Teva, resolving pending claims in three separate federal court antitrust lawsuits, including the Lidoderm matter. The settlement agreement prohibits Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs. The order specifically prohibits Teva from entering into agreements that include reverse payments in the form of: (1) side deals, in which the generic receives compensation through a business transaction entered at the same time as a patent litigation settlement; or (2) a no-Authorized Generic commitment, in which a brand company agrees not to compete with an Authorized Generic version of a drug for a period of time. The global settlement ends this litigation.

**Federal Trade Commission v. Endo Pharmaceuticals Inc., et al.**, Case No. 2:16-cv-01440-PD (E.D. Pa.), FTC File No. 1410004 (complaint seeking a permanent injunction and other equitable relief filed March 30, 2016) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0004/endo-pharmaceuticals-impax-labs>). The complaint charged that Endo Pharmaceuticals Inc. entered anticompetitive reverse-payment settlements between 2010 and 2012 on its two bestselling branded pharmaceuticals products, Opana ER and Lidoderm, and further that Endo used the settlements in order to unlawfully maintain its monopoly on each drug. The complaint alleged that, in each case, Endo paid the generic company eligible for first-filer exclusivity and that the generic company agreed not to market its generic product for a period of time in exchange for a no-AG commitment—in which Endo agreed not to sell an authorized generic (or AG) for at least the first six months of generic sales—and other compensation. Other companies named in the complaint were Impax Laboratories, Inc. (the first generic on most dosages of Opana ER), Watson Laboratories, Inc./Allergan plc (the first generic for Lidoderm), and Teikoku Pharma USA, Inc./Teikoku Seiyaku Co., Ltd. (Endo's partner for Lidoderm). The complaint also charged that the no-AG commitment on generic Lidoderm independently violated the antitrust laws and resulted in reduced competition and higher prices for generic Lidoderm. With the complaint, the Commission filed a settlement with the Teikoku entities, in which they agree not to enter into similar reverse-payment agreements for a period of 20 years. Against the remaining defendants, the Commission sought injunctive and other equitable relief, including equitable monetary relief.

In October 2016, after the Judge severed the Lidoderm and Opana ER claims, the Commission dismissed this action. Subsequently, the Commission settled its claims with Endo by Endo agreeing not to enter similar reverse-payment settlements for a period of ten years. The Commission then filed a complaint against Watson/Allergan covering the Lidoderm claims in the Northern District of California (**Federal Trade Commission v. Allergan PLC, et al.**, Case No. 17-cv-00312 (N.D. Cal.), FTC File No. 1410004) and an administrative complaint against Impax covering the Opana ER claims. (**Impax Laboratories, Inc.**, D-9373, FTC File No. 1410004).

**Federal Trade Commission v. AbbVie Inc., et al.**, 329 F. Supp. 3d 98 (E.D. Pa. 2018), *aff'd in part, rev'd in part and remanded*, 976 F.3d 327 (3d Cir. 2020), *cert. denied sub nom.*, *AbbVie*

*Inc. v. Federal Trade Commission*, No. 20-1293, 2021 WL 2519407, at \*1 (U.S. June 21, 2021); (global settlement entered with Teva February 19, 2019; reverse payment claim against AbbVie withdrawn July 30, 2021) (<https://www.ftc.gov/news-events/press-releases/2021/07/ftc-withdraws-remaining-case-against-abbvie-after-supreme-court-decision>). The complaint charged several major pharmaceutical companies with illegally blocking consumers' access to lower-cost versions of the blockbuster drug AndroGel, a brand-name testosterone replacement therapy for men with low testosterone. The complaint alleged that the AbbVie Defendants (AbbVie Inc., Unimed Pharmaceuticals, LLC (now a wholly-owned subsidiary of AbbVie), Abbott Laboratories) and Defendant Besins Healthcare Inc., filed baseless patent infringement lawsuits against Defendant Teva Pharmaceuticals USA, Inc. and Perrigo Co.— potential generic competitors — to unlawfully maintain and extend their monopoly power on AndroGel by delaying the introduction of lower-priced versions of the drug. Under federal law, these lawsuits triggered an automatic 30-month stay of the FDA's authority to approve the generics' applications to market their testosterone gel products, regardless of the merits of the infringement claims. The complaint further alleged that while the lawsuits were pending, the AbbVie Defendants entered into an anticompetitive settlement agreement with Teva to further delay generic drug competition. According to the complaint, Teva concluded that it would be better off by sharing in the AbbVie Defendants' monopoly profits from the sale of AndroGel than by competing. Thus, Teva settled the baseless infringement lawsuit by entering an agreement with the AbbVie Defendants to delay launching its alternative to AndroGel. In return, the AbbVie Defendants paid Teva in the form of a highly profitable authorized generic deal for another product, executed on the same day as the AndroGel patent litigation settlement.

In May 2015, the district court dismissed the reverse-payment claim, concluding that the patent settlement agreement with Teva was an anticompetitive reverse payment.

In September 2017, the district court awarded partial summary judgment on the FTC's sham litigation claim, ruling that the patent infringement lawsuits filed by the AbbVie Defendants and Besins were objectively baseless. In February 2018, the FTC tried its case to the court on the remaining issues: (1) whether the AbbVie Defendants and Besins used their objectively baseless lawsuits as anticompetitive weapons; (2) whether they had market power; and (3) the appropriate relief, if any.

In June 2018, the court found in the FTC's favor and held that the AbbVie Defendants and Besins violated section 5(a) of the FTC Act. The court held that the FTC established that Defendants illegally and willfully maintained their monopoly power through the filing of sham litigation. The sham litigation delayed the entry of generic AndroGel to the detriment of consumers. The court awarded equitable monetary relief to the FTC in the amount of \$448 million and also awarded \$46 million in prejudgment interest. The AbbVie Defendants and Besins appealed the district court's ruling on the sham litigation claim to the Third Circuit. The FTC also appealed the district court's dismissal of the reverse-payment claim, as well as certain remedy issues.

In February 2019, the Commission reached a global settlement with Teva, resolving pending claims in three separate federal court antitrust lawsuits, including the reverse-payment claim against Teva in the AbbVie matter. The settlement agreement prohibits Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced

generic drugs. The order specifically prohibits Teva from entering into agreements that include reverse payments in the form of: (1) side deals, in which the generic receives compensation through a business transaction entered at the same time as a patent litigation settlement; or (2) a no-Authorized Generic commitment, in which a brand company agrees not to compete with an Authorized Generic version of a drug for a period of time

In a September 2020 opinion, the Third Circuit affirmed the district court's finding of liability on the FTC's sham litigation claim and reinstated the FTC's reverse payment claim. The Third Circuit also reversed the district court's nearly half-billion-dollar monetary judgment for consumers, holding that the FTC is not entitled to disgorgement under 13(b) of the FTC Act.

During the summer of 2021, the Supreme Court denied AbbVie Defendants and Besins' petition for certiorari on the sham litigation claim, and the FTC withdrew its reverse-payment claim from federal district court, thus ending the FTC's litigation against the AbbVie Defendants.

**Federal Trade Commission v. Cephalon, Inc.**, 551 F. Supp. 2d 21 (D.D.C. 2008) (complaint filed February 13, 2008); (transferred to E.D. Pa. April 28, 2008) (stipulated order for permanent injunction and equitable relief filed June 17, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/061-0182/cephalon-inc>). The complaint alleged that Cephalon engaged in an anticompetitive course of conduct to prevent the entry of lower-cost generic competition to Provigil, its branded prescription drug used to treat certain sleep disorders, forcing patients and other purchasers to pay hundreds of millions of dollars a year more for Provigil. According to the complaint, Cephalon unlawfully protected its Provigil monopoly through a series of unlawful settlements with four generic drug makers, all of whom were first to challenge the Provigil patent (considered first filers by the FDA for generic Provigil). 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.

In late 2005 and early 2006, facing the imminent threat of generic competition to its highest selling product, the complaint charged that Cephalon paid these four generic rivals to settle their pending patent litigation and forgo entry for six years, until April 2012. These reverse payments took the form of numerous business transactions, negotiated and executed at the same time that Cephalon settled its patent suits. In these transactions, the complaint alleged that Cephalon agreed to pay the four generic companies a total of more than \$200 million, purportedly for the purchase of active pharmaceutical ingredient, the licensing of intellectual property, and the co-development rights in a new drug. With these large payments, the complaint charged that Cephalon secured six years of protection from generic drug competition that its patent could not provide. During this six-year period, the complaint alleged that consumers paid substantially higher prices for Provigil than if generic entry had occurred. These supracompetitive prices resulted in significant ill-gotten profits for Cephalon.

In January 2015, the district court denied Cephalon's motion for summary judgment. In its opinion, the court applied the legal framework set forth in *Actavis*, the "familiar antitrust rule of reason," where "[p]laintiffs must present evidence of a large reverse payment," which then shifts the burden to defendants "to justify the reverse payment as procompetitive." *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223 (2013). The court concluded that the FTC presented

sufficient evidence to establish that “the side agreements between Cephalon and the [g]eneric [d]efendants were a means of disguising payments for delay and/or inducing the [g]eneric [d]efendants to stay off of the market.”

Under the terms of the stipulated order for permanent injunction and equitable monetary relief, Teva Pharmaceutical Industries, Ltd., which acquired Cephalon in 2012, was required to pay \$1.2 billion to compensate purchasers who overpaid because of Cephalon’s illegal conduct. The stipulated order also prohibits Teva from entering into the type of reverse payments that

Cephalon used to protect Provigil. Specifically, it prohibits agreements in which the branded drug manufacturer makes a monetary payment or otherwise compensates the settling generic and (1) makes that transfer of value expressly contingent on settlement of existing patent litigation, or (2) the transfer occurs 30 days before or after the patent settlement. The stipulated order also describes certain arrangements that are excluded from the ban.

**Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al.**, (Generic AndroGel), Case No. CV-09-00598 (C.D. Cal.), FTC File No. 0710060 (complaint filed January 27, 2009) (transferred to N.D. Ga. April 2009). **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**, 133 S. Ct. 2223 (U.S. Supreme Court reversed and remanded June 17, 2013) (global settlement with Teva reached February 19, 2019; settlement with Solvay reached February 28, 2019) (<https://www.ftc.gov/enforcement/cases-proceedings/071-0060/watson-pharmaceuticals-inc-et-al>). The FTC filed a 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 best-selling product, branded testosterone-replacement drug AndroGel. The complaint charged that Solvay acted unlawfully to eliminate the threat of generic competition by paying Watson and Par a share of its AndroGel profits in exchange for abandoning their patent challenges and agreeing not to compete with generic AndroGel until 2015. 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.

In February 2010, the district court granted defendants’ 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. On April 24, 2012, the Eleventh Circuit upheld the district court’s ruling. On June 17, 2013, the Supreme Court reversed the Eleventh Circuit, rejected the scope of patent test, and held that “reverse settlement agreements” between brand and generic drug companies are subject to antitrust scrutiny under a rule of reason analysis. The Court remanded the case to the U.S. District Court for the Northern District of Georgia for further proceedings consistent with its ruling.

On February 2, 2017, the FTC settled with Endo Pharmaceuticals Inc. in a case pending in the Northern District of California. Included in this settlement was a resolution of the FTC’s claims against Par Pharmaceutical Companies, which was by then owned by Endo Pharmaceuticals Inc.



Thus, on February 7, 2017, the FTC voluntarily dismissed its claims against both Par and Paddock in the litigation in the Northern District of Georgia.

In September 2017, the remaining Defendants filed three motions for summary judgment against the FTC. On June 14, 2018, Judge Thrash denied Defendants' summary judgment motions, holding that there was sufficient evidence to create a genuine issue of material fact as to whether the remaining Defendants entered an agreement to restrain trade, and whether the alleged reverse-payment agreements had anticompetitive effects. Trial was set to begin on March 4, 2019.

On February 19, 2019, the Commission reached a global settlement with Watson's parent company, Teva, resolving pending claims in three separate federal court antitrust lawsuits including *Actavis*. The settlement agreement prohibits Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs. The order specifically prohibits Teva from entering into agreements that include reverse payments in the form of: (1) side deals, in which the generic receives compensation through a business transaction entered at the same time as a patent litigation settlement; or (2) a no-Authorized Generic commitment, in which a brand company agrees not to compete with an Authorized Generic version of a drug for a period of time. Judge Thrash entered a stipulated order with respect to claims against Watson on February 25, 2019. The order will remain in effect for ten years.

On February 28, 2019, the Commission reached a settlement with Solvay. The settlement covers those products that Solvay may have been marketing or developing before its purchase in 2010 by Abbott Laboratories, which later spun off its worldwide pharmaceutical business into AbbVie Inc. Under the settlement, Solvay's current owner AbbVie is prohibited from entering into certain patent settlement agreements that restrict generic entry for certain drugs and contain common forms of reverse payments, such as: (1) a side deal, in which the generic company receives compensation in the form of a business transaction entered at the same time as the patent litigation settlement; and (2) a no-Authorized Generic commitment, in which a brand company agrees not to compete with an Authorized Generic version of a drug for a period of time. Judge Thrash entered an order for a permanent injunction against Solvay on February 28, 2019, resulting in the dismissal of the claims against Solvay. The order will remain in effect for ten years.

**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) (<http://www.ftc.gov/enforcement/cases-proceedings/081-0156/ovation-pharmaceuticals-inc-dba>).

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.) At the time of the purchase, Ovation already held rights to Indocin I.V., another drug used to treat PDA. The Commission's complaint charged 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. The complaint charged 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. The complaint sought 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. On August 19, 2011, the Eighth Circuit affirmed the district court's decision.

**Federal Trade Commission v. 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)); rev'd 402 F.3d 1056 (11<sup>th</sup> Cir. 2005); order denying rehearing *en banc* issued May 31, 2005 (Pet. App. 36a-153a (unreported); Petition for Certiorari filed August 2005. Supreme Court denied petition on June 26, 2006 (<https://www.ftc.gov/enforcement/cases-proceedings/9910256/schering-plough-corporation-upsher-smith-laboratories-american>). 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 Upsher 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 its 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.

**Bristol-Myers Squibb Company**, C-4076, FTC File No. 0110046 (final order issued April 14, 2003) (<https://www.ftc.gov/enforcement/cases-proceedings/0110046/bristol-myers-squibb-company-matter>). The Commission charged in its complaint that Bristol engaged in a pattern of anticompetitive activity over a 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 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, which 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 settling the charges contains general prohibitions concerning conduct relating to Orange Book listings (detailed in the Commission's 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**, C-4060, FTC File No. 0110094 (final order issued October 2, 2002) (<https://www.ftc.gov/enforcement/cases-proceedings/011-0094/biovail-corporation>). 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 settling the charges 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.

**American Home Products** (Schering/ESI), D-9297, 133 F.T.C. 611 (final order issued April 2, 2002) (<https://www.ftc.gov/enforcement/cases-proceedings/american-home-products-corporation>). 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 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.**, Docket No. 9293, FTC File No. 9810368 (final order issued May 8, 2001) (<https://www.ftc.gov/enforcement/cases-proceedings/9810368/hoechst-marion-roussel-inc-carderm-capital-lp-andrx>). 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/Geneva Pharmaceuticals, Inc.**, C-3945, C-3946, FTC File No. 9810395 (final 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.

**Federal Trade Commission v. Mylan Laboratories et al.**, 62 F. Supp. 2d 25 (D.D.C.) (order and stipulated permanent injunction, approved February 9, 2001) (<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. 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**

**Endo Pharmaceuticals Inc./Amneal Pharmaceuticals, Inc.**, FTC File No. 1910104 (complaint filed on January 25, 2021; complaint dismissed on March 30, 2022) (<https://www.ftc.gov/news-events/press-releases/2021/01/ftc-again-charges-endo-impax-illegally-preventing-competition-us>). In this case, the FTC filed a complaint against Endo Pharmaceuticals, Inc., Endo International plc, Impax Laboratories, LLC, and Amneal Pharmaceuticals, Inc., alleging that a 2017 agreement between Endo and Impax eliminated competition in the market for oxymorphone extended-release (ER). The complaint charges all defendants with unfair methods of competition in violation of Section 5 of the FTC Act.

Following a June 2017 request from the FDA, Endo voluntarily withdrew its Opana ER product, leaving Impax's generic version of the original formulation of Opana ER as the only extended-release oxymorphone drug on the market. Endo explored options to bring another oxymorphone ER drug to the market, but ultimately, Endo reached an agreement in August 2017 with Impax. According to the complaint, that agreement, under which Impax shares its monopoly profits with Endo, eliminates Endo's financial incentive to enter the market. The agreement allowed Impax to exercise and maintain monopoly power in the market for FDA-approved oxymorphone ER tablets, according to the complaint.

The complaint seeks monetary and injunctive relief to undo the ongoing competitive effects from this agreement, and a permanent injunction to prohibit Endo, Impax, and Amneal from engaging in similar anticompetitive conduct in the future. On March 30, 2022, the district court dismissed the complaint. On August 25, 2023, the Court of Appeals for the D.C. Circuit affirmed the district court's decision.

**Federal Trade Commission v. Endo Pharmaceuticals Inc., et al.** (See Section II A for citation and annotation.)

**Federal Trade Commission v. AbbVie Inc., et al.** (See Section II A for citation and annotation.)

**Par Pharmaceutical, Inc./Concordia Pharmaceuticals Inc.**, FTC File No. 1510030 (final order issued October 20, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0030/concordia-healthcare-par-pharmaceutical>). The complaint charged that Par and Concordia entered an unlawful agreement that Concordia would refrain from launching an "authorized

generic” version of its brand-name drug Kapvay in exchange for a share of the supra-competitive profits Par would earn as the sole seller of generic Kapvay. Kapvay is a non-stimulant medication for the treatment of attention deficit hyperactivity disorder. According to the complaint, a brand-name drug manufacturer is permitted to market a generic version of its branded product during the first filer’s exclusivity period. Such generics are commonly known as “authorized generics.” Brand-name drug companies introduce authorized generics upon entry of the first generic to maintain some of the revenue it would otherwise lose to the generic competitor. By agreeing not to compete, the complaint charged that Par and Concordia, the only two firms permitted to market a generic Kapvay at the time, deprived consumers of the lower prices that occur with generic competition.

According to the complaint, Par filed an application seeking FDA approval to sell a generic version of Kapvay in March 2011. Concordia acquired the rights to Kapvay in May 2013. Par and Concordia entered into a “License Agreement” approximately five weeks before the Kapvay patent’s October 2013 expiration date. Under the agreement, the complaint alleged that Concordia agreed not to market an authorized generic version of Kapvay for five years. Par in turn agreed to pay Concordia at least 35% (and as much as 50%) of the net profits from the sale of Par’s generic Kapvay product. The parties provided no evidence that Concordia held any rights that might have prevented Par from selling generic Kapvay after expiration of the patent.

The orders settling charges prohibit Par and Concordia from (1) enforcing the relevant provisions of their 2013 License Agreement and (2) entering into similar “no-authorized-generic” agreements in the future. Specifically, the Par order prohibits Par from seeking to enforce any provision in its 2013 License Agreement with Concordia that restricts Concordia’s ability to market an authorized generic Kapvay product. In addition, Par may not enter into any agreement that (1) limits a brand-name drug manufacturer’s ability to market an authorized generic version of a drug product for which Par is seeking FDA approval to sell a generic counterpart; and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question. The Concordia order requires Concordia to relinquish all rights to payment under the License Agreement. It also bars Concordia from entering any agreement with a generic applicant for a reference-listed drug for which Concordia holds the NDA, if the agreement (1) limits marketing of an authorized generic version of that drug and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question.

**Federal Trade Commission v. Cephalon, Inc.** (See Section II A for citation and annotation.)

**Federal Trade Commission v. Boehringer Ingelheim Pharm., Inc.**, 286 F.R.D. 101 (D.D.C. 2012), *aff’d in part, vacated in part*, 778 F.3d 142 (D.C. Cir. 2015), *remanded to*, 1:09-mc-00564 (D.D.C. 2016), *aff’d*, 16-5356 (D.C. Cir. 2018) (<https://www.ftc.gov/enforcement/cases-proceedings/091-0023/boehringer-ingelheim-pharmaceuticals-inc>). In its investigation, the FTC sought to examine whether a patent litigation settlement and a simultaneously executed co-promotion agreement between Boehringer and Barr together constituted an unlawful agreement to compensate Barr for delaying competitive entry. At the time of the agreements, the FTC alleged that Boehringer marketed two branded products: Mirapex, used to treat the symptoms of Parkinson’s disease, and Aggrenox, used to prevent excessive blood clotting and reduce the risk of stroke. Under the August 2008 settlement agreements, Barr agreed not to market generic Mirapex until January 2010 and generic Aggrenox until July 2015. At the same time, the FTC

alleged that the companies entered into a co-promotion agreement in which Boehringer agreed to provide substantial compensation to Barr “ostensibly” in exchange for its efforts promoting branded Aggrenox to women’s health doctors.

As part of its investigation, the FTC issued an administrative subpoena seeking various documents and communications relating to the settlement. When Boehringer failed to comply, the FTC initiated an enforcement proceeding in the District Court for the District of Columbia. Although Boehringer ultimately certified compliance with the subpoena, it withheld hundreds of responsive documents under the work product doctrine and the attorney-client privilege. In September 2012, the District Court held that the documents relating to the settlement were protected from disclosure as work product or under the attorney-client privilege. In a subsequent opinion issued in October 2012, the District Court further held that Boehringer’s failure to conduct centralized, electronic searches was inadequate to respond to the subpoena and required Boehringer to restore and electronically search back-up tapes. The FTC appealed the District Court’s application of the work product doctrine, as it related to financial analysis of the co-promotion agreement, forecasting analysis regarding Barr’s generic product, and the financial analysis used to evaluate the settlement agreement.

In February 2015, the Court of Appeals for the District of Columbia affirmed that the bulk of the contested co-promotion materials were prepared “in anticipation” of the Boehringer-Barr litigation. The Court of Appeals remanded the matter so the district court could “determine in light of the correct legal standards,” which of certain other contested financial and business documents “may be produced, in full or in redacted form, as factual work product.” In September 2016, the District Court held that the vast majority of the documents at issue on remand were fact work product for which the FTC had shown substantial need but that many communications were nonetheless protected from disclosure under the attorney client privilege. The FTC appealed the issue of attorney-client privilege. On June 19, 2018, a three-judge panel of the Court of Appeals for the District of Columbia held that the magistrate’s finding that the attorney-client privilege applied to the communications at issue was not clearly erroneous.

**Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al.**, (Generic AndroGel), **In re AndroGel Antitrust Litigation (No. II)**, **Federal Trade Commission v. Actavis** (See Section II A for citation and annotation.)

**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 the reporting requirements of the Medicare Modernization Act<sup>6</sup> (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

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<sup>6</sup> 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).



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 have been 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-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 pled 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 at the time for BMS's civil violations.

**Federal Trade Commission v. Warner Chilcott Corporation**, Civil Action No. 1:05-CV-2179-CKK (D.D.C) (final order and stipulated permanent injunction approved November 27, 2007) (<https://www.ftc.gov/enforcement/cases-proceedings/0410034/warner-chilcott-holdings-company-iii-ltd-warner-chilcott>). 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. In 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.

**Federal Trade Commission v. Perrigo Company and Alpharma Inc.**, Civil Action No. 1:04CV01397 (RMC) (D.D.C.) (final order and stipulated permanent injunction approved August 24, 2004, modified June 23, 2006) (<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 million 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.

**Federal Trade Commission v. Schering-Plough Corporation, et. al.** (See Section II A for citation and annotation.)

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

**Biovail Corporation/Elan Corporation**, C-4057, File No. 0110132, 134 F.T.C. 302 (final order issued August 15, 2002) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-134#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.

**American Home Products** (See Section II A for citation and annotation.)

**Hoechst Marion Roussel, Inc./Carderm Capital L.P./Andrx Corp.** (See Section II A for citation and annotation.)

**Abbott Laboratories/Geneva Pharmaceuticals, Inc.** (See Section II A for citation and annotation.)



### C. Other Anticompetitive or Unfair Arrangements

**In the Matter of Caremark Rx; Zinc Health Services; et al. (Insulin)**, FTC File No. 2210114, Docket No. 9437 (administrative case filed September 20, 2024) (<https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices>). The administrative complaint alleges that three pharmacy benefit managers (PBMs)—CVS Health’s Caremark, Cigna’s Express Scripts, and United Health Group’s Optum, and their respective group purchasing organizations (GPOs)—have engaged in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin drugs, impaired patients’ access to lower list price products, and shifted the cost of high insulin list prices to vulnerable patients.

As the complaint alleges, the PBMs’ creation of exclusionary drug formularies in 2012 allowed them to begin threatening to exclude certain drugs from formularies to extract higher rebates from drug manufacturers. Because securing formulary coverage was critical for drug manufacturers to access patients with commercial health insurance, the complaint alleges that manufacturers increased list prices to provide the larger rebates and fees necessary to compete for formulary access. Accordingly, even when lower list price insulins became available that could have been more affordable for vulnerable patients, the complaint charges that the PBMs systemically excluded those drugs from formulary coverage in favor of the higher list price insulin products that generate higher rebates and fees for the PBMs and GPOs.

In principle, these rebates should have significantly reduced the cost of insulin drugs for patients at the pharmacy counter. Certain insulin patients, however—such as those with deductibles and coinsurance—often must pay based on the unrebated higher list price and do not benefit from rebates at the point of sale. As a result, they may pay more out-of-pocket than the entire net cost of the drug to the commercial payer. The complaint alleges that by incentivizing manufacturers to inflate insulin list prices, restricting patients’ access to more affordable insulins on drug formularies, and shifting the cost of high list price insulins to vulnerable patient populations, the PBMs and their GPOs engaged in unfair methods of competition and unfair acts or practices under Section 5 of the FTC Act.

## III. CONDUCT INVOLVING PHARMACEUTICAL DISTRIBUTION

### A. Monopolization

**Federal Trade Commission v. Cardinal Health**, Case 15-cv-3031, FTC File No. 1010006 (final order issued April 23, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/101-0006/cardinal-health-inc>). In April 2015, the FTC filed a stipulated permanent injunction in federal court settling charges that Cardinal Health, Inc. excluded potential entrants and maintained monopoly power in 25 local markets for the sale and distribution of low energy radiopharmaceuticals, by obtaining *de facto* exclusive rights to distribute an essential input, heart perfusion agents, from the only two manufacturers. Low energy radiopharmaceuticals are drugs containing radioactive isotopes used by hospitals and clinics for nuclear imaging and other procedures. Radiopharmacies, including Cardinal’s, distribute and sell radiopharmaceuticals to hospitals and clinics, which rely on radiopharmacies to compound radiopharmaceuticals and to

provide just-in-time delivery on a daily basis for procedures. At the time of the complaint, Cardinal owned the nation's largest chain of radiopharmacies.

According to the complaint, a radiopharmacy could not profitably operate and compete in a local market without obtaining the right to distribute heart profusion agents from one of the two manufacturers. Cardinal employed various tactics to induce or coerce the only two manufacturers of heart profusion agents to refuse to grant distribution rights to potential entrants in the 25 markets in which Cardinal operated the only radiopharmacy. Cardinal's coercive tactics did not enhance efficiency or otherwise serve procompetitive ends, but rather had the purpose and effect of insulating Cardinal's downstream monopolies from competition. The complaint alleged that Cardinal's conduct enabled it to amass substantial ill-gotten gains by charging hospitals and clinics in the 25 geographic markets supra-competitive prices.

Under the terms of the final order and stipulated permanent injunction, Cardinal was required to disgorge its ill-gotten gains by paying \$26.8 million into a fund for distribution to customers injured by its conduct. The order bars Cardinal from engaging in similar conduct in the future and requires Cardinal to notify the Commission before entering into new exclusive distribution agreements or buying radiopharmacy assets that would not otherwise be subject to the notification requirements of the Hart-Scott Rodino Act. The order also contains provisions designed to facilitate entry and restore competition in six of the relevant markets where Cardinal continues to operate as the sole or dominant radiopharmacy.

## **B. Agreements on Price and Price-Related Terms**

**Cooperativa de Farmacias Puertorriqueñas (Coopharma)**, C-4374, FTC File No. 1010079 (final order issued November 6, 2012, modification of order issued December 6, 2024) (<https://www.ftc.gov/news-events/news/press-releases/2024/12/ftc-approves-modification-cooperativa-de-farmacias-puertorriquenas-final-commission-order>). The complaint alleged that Cooperativa de Farmacias Puertorriqueñas (Coopharma), a Puerto Rico cooperative of approximately 300 pharmacy-owners, 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. According to the complaint, since at least 2007, Coopharma had negotiated with more than 10 payers over reimbursement rates and signed "single-signature" master contracts on behalf of its member pharmacies. On November 6, 2012, the FTC issued a final order prohibiting Coopharma from entering into or facilitating agreements between or among any pharmacies to negotiate on behalf of any pharmacy with any payer and refuse to deal with any payer. The order also prohibited Coopharma from facilitating information exchanges between pharmacies regarding whether to contract with a payer and inducing anyone to engage in the prohibited conduct.

On August 7, 2024, Coopharma petitioned the Commission to reopen and modify the 2012 order, in part because of changes to a Puerto Rican law that exempts health care cooperatives, like Coopharma, from federal antitrust scrutiny. On December 6, 2024, the Commission granted the petition and modified the order to permit Coopharma to jointly negotiate with insurers and PBMs on behalf of pharmacies to the extent that the entity appointed by Puerto Rico supervises the negotiations according to Puerto Rico's statutory and regulatory framework, concluding that such conduct would qualify for state action immunity.

**Minnesota Rural Health Cooperative**, C-4311, FTC File No. 0510199 (final order issued December 28, 2010) (<http://www.ftc.gov/enforcement/cases-proceedings/051-0199/minnesota-rural-health-cooperative-matter>). The complaint charged that competing hospitals, physicians, and pharmacies in rural southwestern Minnesota agreed to fix prices and collectively negotiate contracts – including price terms – with third-party payers in Minnesota through the Minnesota Rural Health Cooperative (MRHC); and that MRHC had undertaken no efficiency-enhancing integration that could justify this conduct. MRHC had about 22 hospital members (representing most of the hospitals and two-thirds of hospital beds) and 114 physician members (who practiced in about 47 clinics) in SW Minnesota. The complaint charged that, since 1996, MRHC negotiated prices and other competitively significant terms with payers in Minnesota on behalf of MRHC physician and hospital members. MRHC and its members refused to negotiate individually with payers. MRHC also threatened to terminate contracts with payers to pressure them to increase reimbursement rates for MRHC physicians and hospitals. The complaint charged that, through its collective negotiations and coercive tactics, MRHC extracted higher payments and other favorable price-related terms from payers. (E.g., one payer agreed to pay MRHC physicians 27% more and MRHC hospitals 10% more, than comparable non-MRHC physicians and hospitals.)

The complaint also alleged that, from early 2005 to late 2007, MRHC represented about 70 pharmacy members in obtaining higher Medicare “Part D” prescription drug program reimbursement levels. The complaint charged that MRHC took advantage of Part D regulations requiring each participating pharmacy benefit management company (PBM) or other payer to include enough pharmacies in its pharmacy benefits plan to ensure that 70% of rural Part D beneficiaries lived no more than 15 miles from a participating pharmacy. MRHC urged member pharmacies not to deal individually with PBMs so as to “leverage” their negotiating power, and negotiated and contracted collectively with at least six PBMs.

The order, among other things, prohibits MRHC from entering into or facilitating agreements between or among physicians, hospitals, or pharmacies: (1) to refuse, or threaten to refuse, to deal with any payer regarding the terms, conditions, or requirements upon which any physician deals, or is willing to deal, with any payer (including, but not limited to, price terms); or (2) to not deal individually with any payer, or to not deal with any payer through any arrangement other than one involving MRHC. The order also prohibits MRHC from submitting to the Minnesota Department of Health for approval any agreement with any payer if MRHC or any of its officers, directors, members, or employees engaged in any acts of coercion, intimidation, or boycott of, or any concerted refusal to deal with, any payer seeking to contract with MRHC – provided, however, that it would not violate the order for MRHC, when negotiating with a payer in compliance with Minnesota Annotated Code § 62R.01, *et seq.*, to: (1) reject any offer or counter-offer, or refuse to contract; or (2) exchange information that is reasonably necessary to contract pursuant to negotiating with any payer. This latter order provision recognizes that Minnesota laws: (1) authorize health care provider cooperatives to contract with purchasers on a fee-for-service basis; (2) specify that, with certain limitations, such contracts are not contracts that unreasonably restrain trade; and (3) establish a process by which the State’s Department of Health is to review and approve or disapprove health care provider cooperatives with third-party payers.

**Asociacion de Farmacias Region de Arecibo**, C-3855, FTC File No. 9810153 (final order issued March 2, 1999) (<https://www.ftc.gov/enforcement/cases-proceedings/9810153/asociacion-de-farmacias-region-de-arecibo-inc-ricardo-lalvarez>). 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**, C-3822, C-3823, FTC File No. 9610005 (final order issued August 11, 1998) (<https://www.ftc.gov/enforcement/cases-proceedings/9610005/institutional-pharmacy-network-evergreen-pharmaceutical-inc-et>). 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 provided 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.**, C-3664, 121 F.T.C. 762 (final order issued June 10, 1996) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-121>). 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./Maryland Pharmacists Association**, D-9262, 117 F.T.C. 95 (final order issued February 25, 1994)

(<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-117>). 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**, D-3410, 116 F.T.C. 51 (final order issued January 15, 1993) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-116>).

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**, D-9227, 115 F.T.C. 492 (final order issued April 22, 1992)

(<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-115>). 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**, D-9227, 114 F.T.C. 327 (final order issued June 20, 1991)

(<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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.**, D-9227, 114 F.T.C. 344 (final order issued June 25, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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.**, D-9227, 114 F.T.C. 367 (final order issued July 1, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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**, D-9227, 114 F.T.C. 171 (final order issued February 8, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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**, D-9227, 114 F.T.C. 182 (final order issued February 8, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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**, D-9227, 114 F.T.C. 372 (final order issued July 1, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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.**, C-3294, 113 F.T.C. 661 (final order issued July 9, 1990) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-113>). 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.**, D-9238, 114 F.T.C. 152 (final order issued February 5, 1991) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-114>). 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**, D-9239, 114 F.T.C. 159 (final order issued February 7, 1991) (<https://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**, D-9239, 114 F.T.C. 167 (final order issued February 7, 1991) (<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.**, C-3295, 113 F.T.C. 669 (final order issued July 9, 1990) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-113>). 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.**, D-3292, 113 F.T.C. 645 (final order issued July 9, 1990) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-113>). 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**, C-3293, 113 F.T.C. 653 (final order issued July 9, 1990) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-113>). 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.**, C-3256, 112 F.T.C. 28 (final order issued July 13, 1989) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-112>). 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.**, C-3257, 112 F.T.C. 15 (final order issued July 12, 1989) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-112>). 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.**, C-3258, 112 F.T.C. 23 (final order issued July 12, 1989) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-112>). 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.

#### **C. Agreements to Obstruct Innovative Forms of Health Care Delivery or Financing**

**Asociacion de Farmacias Region de Arecibo** (See Section III B for citation and annotation.)

### **IV. MERGERS INVOLVING PHARMACEUTICAL PRODUCTS**

#### **A. Horizontal Mergers between Direct Competitors**

**United Healthcare Services, Inc., v. Gilead Sciences, Inc., et al. (In re HIV)**, Brief of Federal Trade Commission as Amicus Curiae in Support of Neither Party, No. 24-1585 (9th Cir. September 24, 2024) ([https://www.ftc.gov/system/files/ftc\\_gov/pdf/In-re-HIV-FTC-](https://www.ftc.gov/system/files/ftc_gov/pdf/In-re-HIV-FTC-)



[AmicusBriefasfiled.pdf](#)). The case involves two alleged reverse-payment agreements between Gilead Sciences and Teva Pharmaceuticals for the HIV drugs Truvada and Atripla. Plaintiffs alleged that Gilead compensated Teva by contractually restoring a lucrative regulatory exclusivity period that Teva had forfeited. In exchange, Teva allegedly agreed to delay its market entry for both drugs. After trial, the jury returned a special verdict finding that Gilead both lacked market power and had not made a large and unjustified reverse payment to Teva.

On appeal to the Ninth Circuit, the FTC filed an amicus brief in support of neither party to address two discrete rulings. The first was the district court's ruling that the size of a reverse payment can be measured by reference to the brand company's monopoly drug profits, or by the size of the overall drug market. The brief explained that the Supreme Court has instead identified the brand's saved litigation costs—a much smaller figure than monopoly or market profits—as the appropriate benchmark for assessing whether a payment is large. The second was the district court's ruling that a defendant found to have tendered a large and unjustified reverse payment can still avoid liability by showing that it would have won the patent suit. The brief explained that the merits of the underlying patent suit are irrelevant to liability in a reverse-payment case because the anticompetitive harm from a reverse payment is preventing the risk of competition—regardless of whether that risk is small. The brief took no position on market power or the ultimate disposition of the appeal, but requested that the Ninth Circuit correct these two legal errors if it reaches the reverse-payment issues.

**Elanco Animal Health/Bayer**, FTC File No. 1910198 (complaint filed on July 14, 2020; final order approved on September 11, 2020) (<https://www.ftc.gov/news-events/press-releases/2020/09/ftc-approves-final-order-requiring-animal-health-product>). The Federal Trade Commission alleged that animal health products supplier Elanco Animal Health, Inc.'s proposed \$7.6 billion acquisition of Bayer Animal Health, Inc. would likely be anticompetitive. Specifically, the Commission's complaint alleged that the proposed acquisition would harm U.S. competition in three markets: (1) low-dose prescription treatments for canine otitis externa, an inflammation of the outer ear in dogs; (2) fast-acting oral treatments that kill adult fleas on dogs; and (3) brand-name cattle pour-on insecticides.

Following a public comment period, the Commission approved a final order settling the Commission's charges. The final order requires Elanco to divest its canine otitis externa treatment, Osrurnia, to Dechra Limited; its fast-acting oral treatment that kills adult fleas on dogs, Capstar, to PetIQ, LLC; and its brand name cattle pour-on insecticide, StandGuard, to Neogen Corporation. Each divestiture requires Elanco to transfer all intellectual property and other related assets to the respective buyer.

Commission staff and the staff of antitrust agencies in Australia, New Zealand, the United Kingdom, Canada, and the European Commission worked cooperatively to analyze the proposed transaction and potential remedies.

**AbbVie Inc. /Allergan plc**, FTC File No. 1910169 (proposed final order accepted for public comment on May 5, 2020) (<https://www.ftc.gov/news-events/press-releases/2020/05/ftc-imposes-conditions-abbvie-incs-acquisition-allergan-plc>). The complaint charged that AbbVie's proposed \$63 billion acquisition of Allergan would violate federal antitrust law. According to the complaint, the proposed acquisition would likely result in substantial competitive harm to

consumers in the market for treatment of exocrine pancreatic insufficiency, or EPI, a condition that results in the inability to digest food properly. The complaint alleged that only four companies sell pharmaceutical products to treat EPI, with AbbVie and Allergan together controlling 95 percent of the market.

The complaint also alleged that the acquisition would eliminate future direct competition between AbbVie and Allergan in the U.S. market for IL-23 inhibitor drugs for the treatment of moderate-to-severe Crohn's disease and moderate-to-severe ulcerative colitis. A small group of companies sells or is developing IL-23 inhibitors, which are a new class of drugs that treat both conditions. Currently, Johnson & Johnson sells Stelara, the only FDA-approved IL-23 inhibitor treatment for both conditions. Only three other companies—AbbVie, Allergan, and Eli Lilly and Company—have IL-23 inhibitors in late-stage development.

Following a public comment period, the Federal Trade Commission approved a final order settling charges that AbbVie's \$63 billion acquisition of Allergan would violate federal antitrust law. The final order requires AbbVie and Allergan to divest to Nestlé, S.A. Allergan's Zenpep and Viokase, which are currently sold to treat EPI. AbbVie and Allergan also are required to divest to Allergan's rights and assets related to brazikumaban IL-23 inhibitor that is in development to treat moderate-to-severe Crohn's disease and ulcerative colitis—to AstraZeneca plc.

Commission staff cooperated with antitrust agencies in Canada, the European Union, Mexico, and South Africa, and worked closely with the staff of the European Commission to analyze proposed remedies. The Commission staff also worked with the offices of several state Attorneys General in its investigation.

**Amneal Pharmaceuticals LLC/Impax Laboratories Inc.**, C-4650, FTC File No. 1810017 (final order approved on July 10, 2018) (<https://www.ftc.gov/enforcement/cases-proceedings/181-0017-c-4650/amneal-holdings-impax-laboratories-matter>). The complaint alleged that the proposed acquisition by Amneal of Impax Laboratories would lessen actual or future competition and increase the likelihood of higher prices in 10 U.S. markets for generic pharmaceutical products including:

- Desipramine hydrochloride to treat depression. Only five companies currently sell generic desipramine hydrochloride tablets in the United States: Amneal, Impax, Heritage Pharmaceuticals, Inc. ("Heritage"), Sandoz, and Teva Pharmaceutical Industries Ltd. ("Teva"). Sales by Teva, Sandoz, and Amneal account for more than 95 percent of the market. Heritage accounts for the remaining 5 percent while Impax only launched its product in late 2017. The Acquisition would reduce the number of suppliers of generic desipramine hydrochloride tablets from five to four and eliminate the most recent entrant into the market.
- Ezetimibe and simvastatin, used to improve cholesterol and lower triglycerides. Only four companies currently sell generic ezetimibe and simvastatin IR tablets in the United States: Amneal, Impax, Dr. Reddy's Laboratories ("Dr. Reddy's"), and Teva. Sales by Impax account for more than half the market, while Dr. Reddy's and Teva share the remainder. Amneal entered the generic ezetimibe and simvastatin IR tablets market at the end of 2017.

The Acquisition would reduce the number of suppliers from four to three and eliminate the most recent entrant.

- Felbamate, an anticonvulsant used in the treatment of epilepsy. Only four companies currently sell generic felbamate tablets in the United States: Amneal, Impax, Alvogen, and Wallace Pharmaceuticals, Inc. (“Wallace”). The Acquisition would reduce the number of suppliers of generic felbamate from four to three.
- Aspirin and dipyridamole, antiplatelet therapy used to reduce the risk of stroke. Only Amneal currently sells generic aspirin and dipyridamole ER capsules in the United States. Impax is one of only a limited number of suppliers capable of entering the market for generic aspirin and dipyridamole ER capsules in the near future.
- Azelastine nasal spray, used to treat seasonal allergies. Three companies currently sell generic azelastine nasal spray: Impax, partnered with Perrigo Company plc (“Perrigo”); Wallace; and Apotex Inc. (“Apotex”). Amneal is one of a limited number of suppliers capable of entering the market in the near future.
- Diclofenac sodium and misoprostol, used to provide pain relief while minimizing gastrointestinal side effects. Four companies, Amneal, Teva, Sandoz, and Exela Pharma Sciences LLC (“Exela”), have approved ANDAs to sell generic diclofenac sodium and misoprostol DR tablets in the United States. In addition, Greenstone LLC, a Pfizer subsidiary, sells an authorized generic version. Sandoz does not sell its product directly to customers and supplies only to a private labeler. The Exela product, marketed by both Eagle Pharmaceuticals, Inc. and Dash Pharmaceuticals LLC, has limited sales. Impax, partnered with Micro Labs Limited, is one of only a few suppliers capable of entering the market for generic diclofenac sodium and misoprostol DR tablets in the near future.
- Fluocinonide-E cream, a corticosteroid used on the skin to reduce swelling, redness, itching, and allergic reactions. Only four companies currently sell generic fluocinonide-E cream in the United States: Impax, Alvogen, Sun Pharmaceutical Industries Ltd. (“Sun”), and Teva. Sun and Teva are the market leaders, while Impax and Alvogen are recent entrants into the market. Amneal is one of only a few suppliers capable of entering the market for generic fluocinonide-E cream in the near future.
- Methylphenidate hydrochloride, a central nervous system stimulant used to treat attention-deficit disorder and attention-deficit/hyperactivity disorder. Only four companies currently sell generic methylphenidate hydrochloride ER tablets in the United States: Teva is the leading supplier with more than 80 percent share, while Mylan N.V. and Trigen each have less than 10 percent share. Amneal’s ANDA was approved in February of 2018, and it has since launched the product. Impax is one of a limited number of suppliers capable of entering the market for generic methylphenidate hydrochloride ER tablets in the near future.
- Olopatadine hydrochloride nasal spray, used to treat seasonal allergies. Three companies currently sell generic olopatadine hydrochloride nasal spray in the United States: Impax, partnered with Perrigo; Sandoz; and Apotex. Amneal is one of only a few suppliers capable of entering the market for generic olopatadine hydrochloride nasal spray in the near future.

The order requires Impax to divest its rights and assets for these 10 products to three other companies.

**C.H. Boehringer Sohn AG & KG/Sanofi**, C-4601, FTC File No. 1610077 (final order issued February 14, 2017) (<https://www.ftc.gov/enforcement/cases-proceedings/161-0077/ch-boehringer-sohn-matter>). The complaint alleged that the proposed acquisition by Boehringer of the Merial animal health business from Sanofi would lessen actual or future competition and increase the likelihood of higher prices in the relevant U.S. markets for companion animal vaccines and cattle and sheep parasiticides. Boehringer is the sixth largest animal health supplier in the world and Merial is the fourth largest supplier.

- Canine vaccines prevent specific illnesses in dogs. The complaint alleged that the proposed acquisition would reduce the number of suppliers in the markets for seven canine vaccines from four to three. The complaint also charged that the proposed acquisition would lessen future competition in the market for *Bordetella bronchiseptica* bacterium, in which Boehringer competed and Merial was the most likely entrant in the near future.
- Feline vaccines prevent diseases common to cats. The complaint alleged that the proposed acquisition would combine the two leading feline vaccine suppliers, reducing the number of competitors from four to three.
- Rabies vaccines are used for both dogs and cats to protect against the rabies virus. The complaint alleged that the proposed acquisition would combine the top two rabies vaccine suppliers, which controlled a combined 75 percent market share, and would reduce the number of rabies vaccine suppliers from four to three.
- Products to prevent and control outbreaks of parasites in cattle. At the time of the complaint, there were only three primary suppliers of these parasiticides, also known as “macrocyclic lactones,” in the U.S. market. The complaint charged that the proposed acquisition would reduce the number of suppliers to two, giving the merged firm a market share of more than 65 percent.
- Products to prevent and control outbreaks of parasites in sheep. At the time of the complaint, Boehringer and Sanofi’s Merial were the two primary suppliers of these parasiticides in the U.S. market. The complaint charged that the acquisition would give the merged firm a market share of more than 78 percent.

The order requires Boehringer to divest its relevant U.S. companion animal vaccine business and its U.S. Cydectin parasiticide product.

**Mylan N.V./Meda AB**, C-4590, FTC File No. 1610102 (final order issued September 7, 2016) (<https://www.ftc.gov/enforcement/cases-proceedings/161-0102/mylan-nv-matter>). The complaint alleged that the proposed acquisition by Mylan of Meda would reduce current competition and likely lead to higher prices in the generic markets for 400 mg and 600 mg felbamate tablets and future competition, including price competition, in the market for 250 mg generic carisoprodol tablets.

- Generic felbamate tablets are used to treat severe refractory epilepsy. At the time of the complaint, generic felbamate tablets were available in 400 mg and 600 mg strengths. Mylan, Meda, and Amneal Pharmaceuticals LLC sold both strengths of generic felbamate tablets in the United States. A fourth firm, CorePharma LLC, had received FDA approval for both strengths, but had not yet marketed them. Thus, the complaint alleged that the proposed acquisition would reduce the number of current suppliers of 400 mg and 600 mg generic felbamate tablets from three to two.
- Generic carisoprodol is a muscle relaxer that blocks pain sensations between the nerves and the brain. At the time of the complaint, Meda and Vensun Pharmaceuticals marketed generic carisoprodol tablets, while Mylan owned the U.S. marketing rights to a generic carisoprodol product that had recently received FDA approval. The complaint alleged that the proposed acquisition would likely eliminate the entry of a third independent market participant, by increasing the likelihood that the combined company would forego or delay the launch of a generic version.

The order requires Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. and return its rights to market generic carisoprodol tablets in the United States to Indicus Pharma LLC.

**Teva Pharmaceutical Industries Ltd./Allergan PLC**, C-4589, FTC File No. 1510196 (final order issued September 7, 2016) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0196/teva-allergan-matter>). The complaint alleged that Teva's proposed \$40.5 billion acquisition of Allergan's generic pharmaceutical business would reduce current and/or future competition and likely lead to higher prices in 79 markets for pharmaceutical products, including anesthetics, antibiotics, weight loss drugs, oral contraceptives, and treatments for a wide variety of diseases and conditions, including ADHD, allergies, arthritis, cancers, diabetes, high blood pressure, high cholesterol, mental illnesses, opioid dependence, pain, Parkinson's disease, and respiratory, skin and sleep disorders. At the time of the complaint, these markets included individual strengths of pharmaceutical products where Teva and Allergan offered competing products as well as 25 products where there would likely be future competition absent the merger because one or both of the parties were developing competing products.

The order requires the parties to divest their rights and assets related to pharmaceutical markets for one or more strengths of the 79 pharmaceutical products to eleven firms. In addition to the product divestitures, to address the anticompetitive effects likely to arise in markets for the 15 pharmaceutical products where Teva supplies active pharmaceutical ingredients to current or future Allergan competitors, the order requires the Teva to offer these existing API customers the option of entering into long-term API supply contracts.

**Hikma Pharmaceuticals/Boehringer Ingelheim Corporation (Roxane Laboratories, Inc.)**, C-4568, FTC File No. 1510198 (final order issued May 4, 2016) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0198/hikma-pharmaceuticals-plc-matter>). The complaint alleged that the proposed acquisition by Hikma Pharmaceuticals PLC of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, "Roxane") from Boehringer Ingelheim Corporation would lessen current competition in the markets for 5 mg, 10

mg, and 20 mg generic prednisone tablets and generic lithium capsules, and future competition in the market for generic flecainide tablets in the United States.

- Generic prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. Generic prednisone is also prescribed as an immunosuppressant medication. The complaint alleged that the proposed acquisition would reduce the number of suppliers of the generic prednisone tablets from five to four likely leading to higher prices.
- Generic lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. The complaint alleged that the proposed acquisition would reduce the number of suppliers of generic lithium carbonate capsules from four to three, likely leading to higher prices.
- Generic flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. At the time of the complaint, four firms, including Roxane, marketed generic flecainide tablets. Hikma owned the U.S. marketing rights to a generic flecainide product that had been filed by Unimark Remedies Limited (URL) with the U.S. Food and Drug Administration. Upon the approval of URL's application, Hikma likely would have been the fifth supplier of generic flecainide tablets. According to the complaint, the proposed acquisition would have eliminated the entry of a fifth independent market participant, thereby (1) increasing the likelihood that the combined entity would forgo or delay the launch of the generic flecainide tablets to which Hikma owned the U.S. marketing rights; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

The order requires Hikma to transfer to Renaissance Pharma, Inc. all of its interests related to 5 mg, 10 mg and 20 mg generic prednisone tablets and all strengths of lithium carbonate capsules. The order also requires Hikma to relinquish to its drug development partner, Unimark Remedies Ltd., all marketing rights in generic flecainide tablets, and to divest its ownership interest in Unimark.

**Lupin Ltd./Gavis Pharmaceuticals LLC and Novel Laboratories, Inc.**, C-4566, File No. 1510202 (final order issued April 20, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0202/lupin-ltd-et-al-matter>). The complaint alleged that the proposed acquisition by Lupin of Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. would lessen current competition in the market for generic doxycycline monohydrate capsules and future competition in the market for generic mesalamine ER capsules in the United States. Gavis and Novel are related companies. Novel researches, develops and manufactures generic pharmaceutical products, which Gavis markets and sells.

- Generic doxycycline is an antibiotic used for treating a variety of different bacterial infections, including respiratory infections, urinary tract infections, severe acne, skin and skin structure infections, Lyme disease, and anthrax. At the time of the complaint, generic doxycycline monohydrate was available in four strengths: 50 mg, 75 mg, 100 mg, and 150 mg. Gavis and Lupin, both recent entrants into the generic doxycycline monohydrate market,



supplied three of the four strengths, 50 mg, 75 mg, and 100 mg. Three other firms also offered generic doxycycline monohydrate products in the United States. All five companies offered the 100 mg strength, but only four companies offered the 50 mg and 75 mg strengths. The complaint charged that the proposed acquisition would combine two of only four companies offering the 50 mg and 75 mg strengths of generic doxycycline monohydrate capsules, likely leading consumers to pay higher prices.

- Mesalamine ER capsules are used to treat ulcerative colitis. At the time of the complaint, Valeant Pharmaceuticals marketed Apriso, the branded version of the product, which was available in a 375 mg formulation. No generic version of mesalamine ER capsules was available in the United States. Lupin and Gavis were developing generic mesalamine ER capsules products, and were two of a limited number of suppliers capable of entering the market in the near future. According to the complaint, the proposed acquisition would likely eliminate an additional independent entrant in the market for generic mesalamine ER, thereby (1) increasing the likelihood that the combined entity would forego or delay the launch of one of the generic mesalamine ER capsule products in development; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

The order requires the parties to divest Gavis's rights and assets relating to doxycycline monohydrate capsules and mesalamine ER to G&W Laboratories.

**Mylan N.V./Perrigo Company plc**, C-4557, FTC File No. 1510129 (modified final order issued February 19, 2016) (proposed acquisition not consummated because Perrigo shareholders rejected Mylan's hostile takeover attempt) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0129-c-4557/mylan-n-v-matter>). The complaint alleged that the proposed acquisition by Mylan of Perrigo would lessen current competition and likely lead to higher prices in the U.S. markets for four generic drugs in which both Mylan and Perrigo either were currently selling the drugs, or had approval of the Food and Drug Administration to do so. Bromocriptine mesylate is used to treat conditions including type 2 diabetes and Parkinson's disease. The complaint charged that the proposed acquisition would reduce the number of firms capable of supplying generic bromocriptine mesylate 2.5mg tablets from three to two. In the market for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel used to treat acne, the proposed acquisition would combine the only two approved ANDA holders. Liothyronine sodium is used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. The proposed acquisition would reduce the number of suppliers of three dosages of generic liothyronine sodium tablets from three to two. Polyethylene glycol 3350 is used to treat occasional constipation. The proposed acquisition would reduce the number of suppliers for generic PEG 3350 OTC oral solution 17gm packets from three to two.

The complaint also charged that the proposed acquisition would lessen future competition and likely reduce price competition by eliminating at least one likely entrant from a very limited pool of future entrants in three generic markets: (1) Acyclovir 5% ointment used to slow the growth and spread of the herpes virus in the body; (2) Hydromorphone hydrochloride extended release tablets in three strengths used to treat moderate to severe pain in narcotic-tolerant patients; and (3) Scopolamine extended release (1 mg/72 hours) transdermal patches used to prevent

symptoms associated with motion sickness and help patients recover from anesthesia and surgery. Because Perrigo shareholders rejected Mylan's unsolicited offer, the transaction was not consummated, and the contemplated divestitures to Alvogen Group Inc. did not occur. The modified order requires Mylan to seek Commission approval before acquiring any amount of Perrigo shares in the next three years.

**Endo International plc/Par Pharmaceutical Holdings, Inc.**, C-4539, FTC File No. 1510137 (final order issued November 10, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0137/endo-international-plc>). The complaint alleged that the proposed acquisition by Endo International plc of Par Pharmaceutical Holdings, Inc. would lessen current competition in the markets for generic glycopyrrolate tablets, used to mitigate the side effects of peptic ulcer medicines, and generic methimazole tablets, used to inhibit the production of excess thyroid hormone. According to the complaint, the proposed acquisition would reduce the number of generic suppliers of glycopyrrolate tablets from three to two, and produce a firm controlling in excess of 63% of the market. The complaint further alleged that the proposed acquisition would reduce the number of generic suppliers of methimazole tablets from four to three, and the combined company would account for 67% of generic methimazole sales. By eliminating competition between Endo and Par, the complaint charged that the proposed acquisition would increase the likelihood that: (1) Endo would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices. The order requires Endo to divest all of its rights and assets related to generic glycopyrrolate tablets and generic methimazole tablets to Rising Pharmaceuticals.

**Pfizer Inc./Hospira, Inc.**, C-4537, FTC File No. 1510074 (final order issued October 15, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0074/pfizer-inchospira-inc>). The complaint alleged that the proposed acquisition by Pfizer Inc. of Hospira, Inc. would lessen current competition in the markets for generic acetylcysteine inhalation solution and clindamycin phosphate injection, and future competition in the markets for voriconazole injection and melphalan hydrochloride injection in the United States. Generic acetylcysteine inhalation solution is a mucolytic therapy used to treat certain respiratory disorders. The complaint alleged that the proposed acquisition would eliminate the current competition between two of the three competitors in the market for generic acetylcysteine inhalation solution, likely leading to price increases. Clindamycin phosphate injection is an antibiotic used to treat lung, skin, blood, bone, joint, and gynecological infections in hospitals. The complaint alleged that the proposed acquisition would reduce the number of suppliers from four to three, likely leading to higher prices. Voriconazole injection is an antifungal medication used to treat significant fungal infections. Pfizer was one of two suppliers of a voriconazole injection product in the U.S. Hospira was one of a limited number of suppliers capable of entering the voriconazole injection market in the near future. Melphalan hydrochloride injection is a chemotherapy agent used to treat multiple myeloma and ovarian cancer. At the time of the complaint, there were two melphalan hydrochloride injection products available in the U.S. The complaint alleged that Pfizer and Hospira were developing melphalan hydrochloride injection products, and were two of a limited number of suppliers capable of entering the market in the near future. The order requires Pfizer to divest all its rights to generic acetylcysteine inhalation solution and Hospira to divest all of its rights and assets related to clindamycin phosphate injection, voriconazole injection, and melphalan hydrochloride injection to Alvogen.



**Eli Lilly and Company/Novartis Animal Health**, C-4500, FTC File No. 1410142 (final order issued February 20, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0142/eli-lilly-company-novartis-ag-matter>). The complaint alleged that Eli Lilly and Company's proposed acquisition of the Novartis Animal Health (NAH) business from Novartis AG would substantially lessen competition and increase the likelihood of higher prices in the market for canine heartworm parasiticides, used to treat heartworm disease in dogs. At the time of the complaint, the market for canine heartworm parasiticides in the United States was highly concentrated. According to the complaint, Eli Lilly's Trifexis and NAH's Sentinel products were particularly close competitors because they both use the same active ingredient to treat heartworm, they are the only combined products that treat fleas as well as heartworm, and they both are oral products. The complaint charged that the proposed acquisition would consolidate the two closest competitors, would substantially increase concentration, and would produce a single firm controlling more than 43% of the canine heartworm parasiticides market. The order requires Eli Lilly to divest the rights and assets related to Novartis's Sentinel products to Virbac S.A.

**Novartis AG/GlaxoSmithKline, PLC**, C-4498, FTC File No. 1410141 (final order issued January 13, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0141-c-4510-c-4498/novartis-ag-matter-glaxosmithkline>). The complaint charged that the proposed joint venture to combine the GlaxoSmithKline, PLC (GSK) consumer healthcare business with most of Novartis AG's consumer healthcare business would reduce competition and likely lead to increased prices in the market for nicotine replacement therapy transdermal patches (nicotine replacement patches). At the time of the complaint, Novartis and GSK were the only suppliers of branded nicotine replacement patches in the U.S. GSK's branded nicotine replacement patches were marketed under the NicoDerm CQ® brand, and Novartis's were marketed under the Habitrol® brand. GSK and Novartis also were two of only three suppliers of private label nicotine replacement patches in the U.S. The complaint charged that Novartis's ownership of Habitrol, its private label nicotine patches, and a substantial interest in the joint venture that sold GSK's nicotine replacement patches would substantially reduce competition and lead to higher prices for Novartis's Habitrol and its private label nicotine replacement patches. The order requires Novartis to divest Habitrol, as well as its private-label nicotine replacement patch business, to Dr. Reddy.

**Prestige Brands Holdings, Inc./Insight Pharmaceuticals Corporation**, C-4487, FTC File No. 1410159 (final order issued October 7, 2014) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0159/prestige-brands-holdings-inc-insight-pharmaceuticals>). The complaint alleged that the proposed acquisition by Prestige Brands Holdings, Inc. of Insight Pharmaceuticals Corporation would eliminate the close competition between Dramamine and Bonine, the only two branded over-the-counter motion-sickness drugs with significant sales, likely leading to higher prices for consumers. The order requires Prestige to divest Bonine to Wellspring Pharmaceuticals.

**Actavis PLC/Forest Laboratories, Inc.**, C-4474, FTC File No. 1410098 (final order issued August 29, 2014) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0098/actavis-plc-forest-laboratories-matter>). The complaint alleged that the proposed acquisition by Actavis plc of Forest Laboratories, Inc. would delay the introduction of generic competition to Forest's Lamictal ODT, the branded lamotrigine orally disintegrating tablets used to prevent seizures, and

insulate the branded product from generic competition. At the time of the complaint, Actavis was the only company that had received FDA approval for a generic version of Lamictal ODT. The complaint also charged that the proposed transaction would reduce competition by eliminating a competitor in the markets for generic diltiazem hydrochloride extended release capsules, used to treat hypertension and chronic stable angina; generic ursodiol tablets, used to treat primary biliary cirrhosis of the liver; and generic propranolol hydrochloride extended release capsules, used to treat hypertension. According to the complaint, the acquisition would reduce competition leading to higher prices for consumers and to the elimination of future price competition. The order requires the companies to relinquish their rights to market generic diltiazem hydrochloride to Valeant Pharmaceuticals International, Inc. and sell generic ursodiol and generic lamotrigine ODT to Impax Laboratories, Inc. It also requires Forest to sell its rights to generic propranolol hydrochloride to Catalent Pharma Solutions, Inc.

**Valeant Pharmaceuticals International, Inc./Precision Dermatology, Inc.**, C-4477, FTC File No. 1410101 (final order issued August 20, 2014) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0101/valeant-pharmaceuticals-international-precision-dermatology>). The complaint alleged that the proposed acquisition by Valeant Pharmaceuticals International, Inc. of Precision Dermatology, Inc. would reduce competition in the market for branded and generic single-agent topical tretinoin. At the time of the complaint, Valeant and Precision were the only two significant suppliers of the branded single-agent topical tretinoin and the proposed acquisition would have eliminated competition between them. The companies also were the two largest suppliers of generic Retin-A. The complaint charged that the proposed acquisition would likely give Valeant a monopoly in four of five versions of generic Retin-A and reduce competition in the remaining version. The order settling the charges requires Valeant to sell Precision's assets related to Tretin-X, its branded single-agent topical tretinoin, to Watson Laboratories, Inc. and Precision's assets related to generic Retin-A to Matawan Pharmaceuticals LLC, a subsidiary of Rouses Point Pharmaceuticals, LLC. In addition, both Watson Laboratories, Inc. and Matawan received partial assignments of the manufacturing contracts for both Tretin-X and generic Retin-A.

**Akorn, Inc./Hi-Tech Pharmacal, Inc.**, C-4452, FTC File No. 1310221 (final order issued June 16, 2014) (<http://www.ftc.gov/enforcement/cases-proceedings/131-0221/akorn-hi-tech-pharmacal-matter>). The complaint alleged that Akorn Enterprises, Inc.'s proposed acquisition of Hi-Tech Pharmacal, Inc. would reduce competition and likely lead to higher prices in the generic markets for (1) Ciloxan drops, used to treat bacterial eye infections and corneal ulcers; (2) Quixin drops, used to treat bacterial eye infections; (3) Xylocaine jelly, a topical anesthetic prescription drug; and (4) EMLA cream, a topical anesthetic prescription drug. The complaint also alleged that the proposed acquisition would likely reduce future competition, including price competition, for generic Ilotycin ointment, used to treat bacterial eye infections, by increasing the likelihood that the combined company would forego or delay the launch of a generic version. The order requires the parties to sell either Akorn's or Hi-Tech's rights and assets to each of the five drug products to Watson Laboratories, Inc., and requires Akorn to assign to Watson its contract for making branded and generic EMLA cream.

**Endo Health Solutions, Inc./Boca Pharmacal, LLC**, C-4430, FTC File No. 1310225 (final order issued March 19, 2014) (<http://www.ftc.gov/enforcement/cases-proceedings/131-0225/endo-health-solutions-inc-boca-life-science-holdings-llc-boca>). The complaint alleged that

Endo Health Solutions, Inc.'s proposed acquisition of Boca Pharmacal, LLC would reduce competition and likely lead to higher prices in seven markets for generic drugs. At the time of the complaint, Endo Health Solutions and Boca Pharmacal were two of the few suppliers of (1) PolyViFlor 0.25mg drops; (2) PolyViFlor 0.5mg drops; (3) PolyViFlor 0.25mg drops with iron; and (4) TriViFlor 0.25mg drops. The complaint charged that the proposed transaction would likely reduce existing competition in the markets for these four generic multivitamin drops used to treat children who do not have access to fluoridated water.

The complaint also charged that the proposed acquisition would likely reduce future competition in the generic markets for (1) Bromfed-DM, used to treat symptoms of the common cold; (2) Zamicet, used to relieve moderate to severe pain; and (3) Vosol HC, used to treat swimmer's ear. At the time of the complaint, no company marketed generic versions Bromfed-DM and Zamicet. Endo Health Solutions and Boca Pharmacal were among a limited number of firms that had generic versions of the two drugs in development. Boca Pharmacal also was one of limited number of firms with generic Vosol HC in development. Endo Health Solutions was one of only three suppliers of generic Vosol HC.

The order requires Boca Pharmacal to return to Sonar Products, Inc. all of Boca's rights related to the four generic fluoride multivitamin drops. Sonar owned and manufactured the four generic fluoride multivitamin drops and, prior to the proposed acquisition, Boca Pharmacal had an exclusive marketing and distribution agreement with Sonar for the products. Endo is required to divest to Rhodes Pharmaceuticals, Inc. all of its rights and interests in generic Bromfed-DM and generic Zamicet as well as all of Boca's rights and interests in generic Vosol HC.

**Mylan, Inc./Strides Arcolab Ltd.**, C-4413, FTC File No. 1310112 (final order issued December 12, 2013) (<http://www.ftc.gov/enforcement/cases-proceedings/131-0112/mylan-inc-agila-specialties-global-ptelimited-agila>). The complaint alleged that Mylan's proposed acquisition of Agila Specialties Global Pte. Ltd. and Agila Specialties Pvt. Ltd. (Agila) from Strides Arcolab Ltd. would reduce competition and likely lead to higher prices by reducing existing or imminent competition in the markets for the following six generic injectable products: (1) amiodarone hydrochloride injection, an anti-arrhythmic cardiac drug; (2) etomidate injection, a surgical anesthetic; (3) fluorouracil injection, used to treat breast, pancreatic and other cancers; (4) labetalol hydrochloride injection, used to treat hypertension; (5) mesna injection, used to prevent urinary tract damage caused by a certain chemotherapy drug; and (6) methotrexate sodium preservative-free injection, used to treat several types of pediatric cancers and certain autoimmune disorders. At the time of the complaint, Mylan and Agila were two of the few suppliers of four of the six generic injectable products. With respect to fluorouracil injection and labetalol hydrochloride injection, Mylan and Agila were two of the few companies with approved ANDAs capable of supplying those two generic injectable products in the U.S.

The complaint also alleged that the proposed acquisition would reduce future competition, including price competition, by increasing the likelihood that the combined company would forego or delay the launch of the following four generic injectable products: (1) acetylcysteine injection, used to prevent or minimize liver damage caused by an acetaminophen overdose; (2) fomepizole injection, used to treat accidental poisoning caused by ethylene glycol or methanol ingestion; (3) ganciclovir injection, used to treat patients with weakened immune systems to slow

the growth of a form of herpes that can lead to blindness; and (4) meropenem injection, used to treat serious bacterial infections in the ICU.

Finally, the complaint charged that the proposed acquisition would likely reduce competition in the future for generic mycophenolate mofetil injection, at the time available only as a branded drug and used in transplant medicine to reduce the chance of organ transplant rejection. Since Mylan and Agila were likely to be among a limited number of suppliers when generic entry occurred, the complaint charged that the proposed transaction would reduce the number of likely generic competitors in the market. The order requires Mylan to divest either Mylan or Agila/Strides products as directed in the order.

**Actavis, Inc./Warner Chilcott plc**, C-4414, FTC File No. 1310152 (final order issued December 4, 2013) (<http://www.ftc.gov/enforcement/cases-proceedings/131-0152/actavis-inc-warner-chilcott-plc-matter>). The complaint alleged that the proposed acquisition by Actavis, Inc. of Warner Chilcott plc would eliminate current competition between the two firms in one pharmaceutical market and impede future generic competition in three other markets. The complaint alleged that Actavis and Warner Chilcott were the only two significant suppliers of generic Femcon FE, a chewable oral contraceptive tablet containing progestin and estrogen. Warner Chilcott also manufactured the branded version of the drug. According to the complaint, the reduction in the number of generic suppliers would likely lead to significantly higher prices for this drug. The complaint further charged that Actavis was likely to be one of the first generic suppliers to compete with Warner Chilcott's branded version of three other drugs: (1) Loestrin 24 FE, a low-dose progestin/estrogen combination oral contraceptive; (2) Lo Loestrin FE, also a progestin/estrogen combination oral contraceptive; and (3) Atelvia, a delayed-release tablet used to treat post-menopausal osteoporosis. As a result, the proposed acquisition would likely lead to higher prices because the combined firm would have the ability to delay entry of Actavis' generic product in the three markets.

The order requires Actavis to sell to Amneal Pharmaceuticals LLC all of Actavis' rights and assets related to its generic versions of the three oral contraceptives and the osteoporosis drug. It also requires Actavis to enter into an agreement to supply generic versions of Femcon FE and Loestrin 24 FE to Amneal for two years, after which Amneal may extend the agreement for two more years. Finally, the order requires Actavis to relinquish its claim to first filer marketing exclusivity for generic Lo Loestrin FE and Atelvia to preserve the incentives of companies currently leading the patent litigations against Warner Chilcott related to these products.

**Watson Pharmaceuticals Inc./Actavis, 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 likely substantially reduce competition in 21 generic drug markets. At the time of the complaint, Watson was a global pharmaceutical company based in New Jersey that specialized in the development, production, and marketing of generic and branded drugs as well as active pharmaceutical ingredients (APIs). In the United States, Watson marketed more than 160 generic pharmaceutical product families. Actavis, headquartered in Switzerland, was also a global pharmaceutical company engaged in the development, production, and marketing of generic drugs, APIs and over-the-counter drugs. It marketed 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 were currently sold, eight markets involved generic drug products that either one or both of the companies currently sold or had in development, and both companies had generic products in development in the remaining relevant markets. These 21 generic markets were or were expected to be concentrated, and Watson and Actavis were currently one or expected to be one of only a few competitors.

- **Currently Marketed Products.** The complaint alleged 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 alleged that the proposed acquisition would reduce future competition 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 alleged that the proposed acquisition would reduce competition in the future markets for the following six generic drugs that were not on the market but were 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. 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.

In 2016, Teva acquired Actavis's rights and obligations related to Embeda, a generic version of an abuse-resistant opioid painkiller. The 2012 decision and order required Watson and Actavis to supply Embeda to Pfizer Inc. for a period not to exceed four years after Pfizer's relaunch of Embeda, which occurred in January 2015. The decision and order also required Watson and Actavis to assist in the transfer of technology for manufacturing Embeda to Pfizer or a third party. In October of 2018, Teva petitioned to extend, at Pfizer's request, the Embeda supply agreement for an additional period because Pfizer had not yet completed the technology transfer for Embeda manufacturing to a third party. Without Teva's supply of Embeda, Pfizer would be unable to supply patients with Embeda after December 2018.

On December 17, 2018, the Commission approved the application by Teva to reopen and modify its decision and order.

**Novartis, AG/Fougera Holdings, Inc.**, C-4364, FTC File No. 210144 (final order issued September 5, 2012) (<http://www.ftc.gov/enforcement/cases-proceedings/121-0144/novartis-ag-matter>). In its complaint, the Commission charged 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 reduce 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 alleged 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 offered a generic version of the drug in the United States were Novartis, Fougera and G&W Laboratories. Novartis had the leading market share of 67%, followed by G&W with 22% and Fougera with 11%. Generic lidocaine-prilocaine cream is used as an anesthetic to prevent pain resulting from injections and surgery. At the time of the complaint, the cream was available in 30 gram tubes and packages of five 5 gram tubes, known as 5-5 tubes. The 30 gram tubes were prescribed for home use and the 5-5 tubes were only used in hospitals. Fougera, Hi-Tech Pharmaceutical Co. and Novartis were the only U.S. firms that supplied 30 gram tubes. Novartis and Fougera were the only two U.S. suppliers of the 5-5 tubes. According to the complaint, 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 was likely to facilitate price increases, or eliminate price decreases, by eliminating one of a limited number of suppliers.

Fougera also marketed a branded drug Solaraze, which is used to treat actinic keratosis. The drug is a formulation containing the active ingredient diclofenac sodium. Novartis was best-positioned to become the first generic competitor for the drug. If consummated, the proposed acquisition would likely 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.

**Valeant Pharmaceuticals International Inc./Dermik Laboratories, Inc.**, C-4342, FTC File No. 1110215 (final order issued February 21, 2012) (<https://www.ftc.gov/enforcement/cases-proceedings/1110216/valeant-pharmaceuticals-international-inc-johnson-johnson>). The complaint alleged that Valeant's proposed acquisition of Dermik Laboratories, Inc. from Sanofi would likely substantially 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.

At the time of the complaint, Dermik, Sanofi's dermatological unit, manufactured and marketed BenzaClin. Valeant owned the only Abbreviated New Drug Application for the generic version of BenzaClin, which it licensed to Mylan, Inc. Under the licensing agreement, Mylan sold the generic version of BenzaClin and Valeant received royalties from those sales. At the time of the complaint, in the BenzaClin market, Dermik's sales accounted for approximately 50% of unit sales, while unit sales of Mylan's generic version accounted for the other approximate 50%. The proposed acquisition would create a monopoly in this market. There were 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., marketed generic versions of Efudex, and Valeant also marketed an authorized generic of the drug. Sales of Efudex had almost completely been replaced by sales of the three generic equivalents of the drug, and Dermik's Carac was priced directly against the three generic versions of Efudex. After the acquisition Valeant's share in the topical 5FU market would be over 50%. The complaint alleged that these acquisitions would lead to higher prices for consumers. The order requires Valeant to sell to Mylan all rights to generic BenzaClin. It also requires Valeant to license to Mylan the rights to manufacture and market the authorized general version of Efudex.

**Valeant Pharmaceuticals International Inc./Ortho Dermatologics**, C-4343, FTC File No. 1110216 (final order issued February 8, 2012) (<https://www.ftc.gov/enforcement/cases-proceedings/1110216/valeant-pharmaceuticals-international-inc-johnson-johnson>). The complaint alleged that Valeant's proposed acquisition of Ortho Dermatologics, a division of Johnson & Johnson's Janssen Pharmaceuticals, Inc., would likely substantially lessen competition in the U.S. market for prescription tretinoin emollient creams, which are topical products derived from Vitamin A and used to treat fine line wrinkles. At the time of the complaint, Valeant marketed branded Refissa tretinoin emollient cream and a generic emollient cream pursuant to a license agreement with Spear Pharmaceuticals. Johnson & Johnson's branded Renova was the only other tretinoin emollient cream product on the market. Post-acquisition Valeant would have a monopoly in the U.S. market for tretinoin emollient cream, and higher prices for consumers would likely occur, according to the complaint. The order requires

Valeant to return all marketing rights to Refissa and the generic tretinoin emollient cream to Spear Pharmaceuticals.

**Teva Pharmaceutical Industries Ltd./Cephalon, Inc.**, C-4335, FTC File No. 1110166 (amended final order issued July 3, 2012) (<https://www.ftc.gov/enforcement/cases-proceedings/111-0166/teva-pharmaceutical-industries-ltd-cephalon-inc-matter>). The Commission alleged in its complaint that the proposed acquisition by Teva Pharmaceutical Industries Ltd. of Cephalon, Inc. would reduce competition and lead to higher prices in the following three markets:

- 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 were 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% share of the sales of the generic Actiq product.
- 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. At the time of the complaint, no companies made or marketed a generic version of Amrix; however, Teva and Cephalon were two of only a limited number of suppliers that may have been able to enter the market quickly with a generic product.
- Modafinil tablets, versions of the brand name drug Provigil, which was 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., a generic drug manufacturer based in New Jersey.

In its amended final order issued July 3, 2012, the Commission modified the 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 had launched generic Provigil were Teva and Par, which was supplied by Teva under the order. To assure that the FDA would 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/Paddock Laboratories, Inc.**, C-4329, FTC File No. 1110083 (final order issued June 21, 2012) (<https://www.ftc.gov/enforcement/cases-proceedings/111-0083/perrigo-company-paddock-laboratories-inc-matter>). The complaint charged that the \$540 million acquisition of Paddock Laboratories, Inc. 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:

- 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% of the ammonium lactate cream market and 93% of the ammonium lactate lotion market.
- 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% of this market.
- 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. were 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% of the market for the 12.5 mg strength and 35% of the market for the 25 mg strength.
- Generic clobetasol spray is a topical steroid used to treat moderate psoriasis in adults. Perrigo and Paddock were developing clobetasol sprays and were two of a limited number of suppliers capable of entering this future market in a timely manner.
- Generic diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock were in the process of entering the diclofenac solution market and were among a limited number of suppliers that could enter this future market in a timely manner.
- Testosterone gel is used to treat adult males who have a deficiency or absence of testosterone. Abbott Laboratories marketed testosterone gel under the brand name AndroGel. Perrigo was among a limited number of suppliers capable of entering this future market in a timely manner. According to the complaint, Paddock would receive substantial payments

from Abbott pursuant to an agreement that Par Pharmaceutical Companies, Inc. had with Abbott that related to AndroGel. The complaint alleged that the acquisition would 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. 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 "reverse payment" arrangements with Abbott.

**Hikma Pharmaceuticals PLC**, C-4320, FTC File No. 1110051 (final order issued June 6, 2011) (<https://www.ftc.gov/enforcement/cases-proceedings/111-0051/hikma-pharmaceuticals-plc-matter>). The complaint challenged Hikma Pharmaceuticals PLC's proposed acquisition of Baxter Healthcare Corporation, Inc.'s generic injectable pharmaceutical business, including a manufacturing facility in Cherry Hill, New Jersey and a warehouse and distribution center in Memphis, Tennessee. The complaint alleged that the acquisition by Hikma of the generic injectable phenytoin and promethazine businesses of Baxter. would be anticompetitive and likely would result in higher prices for both drugs. 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 alleged that the U.S. markets for both products were already highly concentrated; Hikma, Baxter and Hospira, Inc. were the only companies that supplied phenytoin and promethazine.

The settlement order requires Hikma to divest certain rights and assets related to generic injectable phenytoin and promethazine to X-Gen Pharmaceuticals Inc., 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.

**Pfizer, Inc./Wyeth**, C-4267, FTC File No. 0910053 (final order issued January 25, 2010) (<https://www.ftc.gov/enforcement/cases-proceedings/091-0053/pfizer-inc-corporation-wyeth-corporation-matter>). The Commission's complaint challenged Pfizer's proposed \$68 billion acquisition of Wyeth, including Wyeth's "Fort Dodge" animal health division. Both firms manufactured human and animal health biological and pharmaceutical agents, with combined worldwide revenues of almost \$72 billion. The complaint charged that the acquisition would substantially lessen competition in the following 21 U.S. markets for animal health products:

- Cattle Health Product Markets. In most markets below, the proposed acquisition would give Pfizer a post-acquisition market share of over 50%.
  - Killed cattle respiratory vaccines, used to prevent respiratory diseases in pregnant cattle without the risk of causing abortion
  - Modified-live cattle respiratory vaccines
  - Cattle reproductive vaccines, used to prevent abortions in pregnant cattle
  - Cattle pasteurella vaccines, used to prevent pneumonia and other respiratory infections in cattle caused by certain bacteria
  - Lactating-cow and dry-cow mastitis treatments
  - Dairy cattle broad-spectrum antibiotics with low milk-withholding times
  - Cattle macrocyclic lactone parasiticides
  - Cattle benzimidazole parasiticides
- Companion Animal Health Product 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% of the market.
  - Canine combination vaccines prevent common canine diseases, such as those caused by canine distemper, adenovirus, parainfluenza, parvovirus, and coronavirus.
  - Canine monovalent parvovirus vaccines, administered as booster shots to puppies
  - Canine monovalent coronavirus vaccines, a \$2.3 million market in the U.S.
  - Canine monovalent leptospira vaccines
  - Canine bordetella vaccines
  - Feline combination vaccines are used to prevent common feline diseases, such as feline panleukopenia, rhinotracheitis, chlamydia, and calcivirus.
  - Feline leukemia vaccines
  - Companion animal rabies vaccines
  - Companion animal cephalosporins
- Equine Health Product Markets.
  - Equine tapeworm parasiticides *containing praziquantel*
  - Equine herpesvirus vaccines
  - Equine joint-injected steroids

The complaint charged that the proposed acquisition would cause significant competitive harm to consumers in the relevant markets by: (1) eliminating competition between Pfizer and Wyeth; (2) increasing the likelihood that Pfizer could unilaterally exercise market power; (3) increasing the likelihood of coordinated action between suppliers; (4) reducing Pfizer's incentives to pursue further research and development; and (5) increasing the likelihood that consumers would 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.

**Novartis AG/Alcon, Inc.**, C-4296, FTC File No. 1010068 (final order issued September 28, 2010) (<https://www.ftc.gov/enforcement/cases-proceedings/101-0068/novartis-ag-matter-alcon-inc>). The Commission's complaint challenged Novartis AG's proposed \$28.1 billion acquisition of Alcon, Inc., from Nestle, S.A. The complaint alleged 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 used during cataract surgery. At the time of the complaint, Novartis and Alcon each produced an injectable miotics product – Miochol-E and Miostat, respectively – for which there was no generic version. Novartis and Alcon were the only suppliers of injectable miotics in the U.S. 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 did not participate in the U.S. injectable miotics market.

**Schering-Plough Corporation/Merck & Co., Inc.**, C-4268, FTC File No. 0910075 (final order issued October 29, 2009) (<https://www.ftc.gov/enforcement/cases-proceedings/091-0075/schering-plough-corporation-corporation>). The Commission's complaint challenged Schering's proposed \$41.1 billion acquisition of Merck. Merck and Schering both supplied a variety of human and animal health products. Merck's animal health products business was carried on through Merial Limited, an equally-owned joint venture of Merck and Sanofi-Aventis S.A. The complaint charged 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 was 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) laryngotracheitis; (9) avian encephalomyelitis; and (10) tenosynovitis. Merck (through



Merial) and Schering were the two largest producers of poultry vaccines in the U.S. Together, Merial and Schering accounted for over 75% of all poultry vaccine sales in the U.S. Three other suppliers accounted 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 were 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.

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.

**Teva Pharmaceutical Industries Ltd./Barr Pharmaceuticals, Inc.**, C-4242, FTC File No. 081 0224 (final 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 were 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 accounted for 73% of the generic tamoxifen citrate market and 55% of the generic cyclosporine liquid market. The proposed acquisition would reduce the number of competitors in each market from three to two.

- 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 were two of only four suppliers supplying all dosage forms of this generic drug. A combined Teva/Barr would possess 82% 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 were two of the leading suppliers of generic carboplatin injection, with a combined market share of 60%.
  - Metronidazole is an anti-infective used in the treatment of a variety of bacterial infections. Barr and Teva had 50% and 39%, 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% 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 had roughly equal shares, and a combined share of 41%.
  - Flutamide is an anti-androgen drug used to treat prostate cancer. In the generic flutamide market, Teva and Barr had shares of 28% and 14%, respectively.
  - Glipizide/metformin is commonly prescribed as a first line treatment for diabetes. Teva and Barr had 26% and 25% 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% of the market.
  - Mirtazapine is an antidepressant used to treat moderate to severe depression. Barr and Teva had 26% and 10%, respectively, of the generic mirtazapine market.
- In two other product markets, the proposed acquisition would eliminate important and significant future competition. Epop is used to treat severe primary pulmonary hypertension. Epop was a new generic market, and Teva was the only generic epop supplier. However, Barr was developing a generic epop product. Fluoxetine weekly capsules were a widely-prescribed antidepressant; and both Teva and Barr had generic products in development for this market. Few other firms were capable of, or interested in, entering these markets.
- Oral contraceptives. Teva's acquisition of Barr would likely lessen competition in 13 oral contraceptive markets, including: two markets in which both Teva and Barr participated; ten markets in which Barr participated and Teva was developing a product; and one market in which both Teva and Barr were developing products, and were among a limited number of firms with this product in development.

The complaint charged 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 were relatively small and in decline, offering limited and insufficient sales opportunities to encourage new entry. 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 (final order issued February 2, 2009) (<http://www.ftc.gov/enforcement/cases-proceedings/081-0240/king-pharmaceuticals-inc-alpharma-inc-matter>). The complaint charged 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 offered the only two competitively significant branded morphine sulphate oral LAOs, which were particularly close competitors within the larger oral LAO market. The complaint charged 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 stated that entry into the market for the manufacture and sale of oral LAOs was 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.

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

**Sun Pharmaceuticals Industries/Taro Pharmaceutical Industries**, C-4230 (final order issued September 16, 2008) (<https://www.ftc.gov/enforcement/cases-proceedings/071-0193/sun-pharmaceutical-industries-ltd-matter-taro-pharmaceuticals>). 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 (final order issued December 28, 2007) (<https://www.ftc.gov/enforcement/cases-proceedings/071-0132/schering-plough-corporation-matter>). 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 (final 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.

**Actavis Group/Abrika Pharmaceuticals, Inc.**, C-4190, FTC File No. 0710063 (final order issued May 18, 2007) (<https://www.ftc.gov/enforcement/cases-proceedings/0710063/actavis-group-hf-abrika-pharmaceuticals-inc-matter>). 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 Actavis 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, FTC File No. 0710002 (final 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, FTC File No. 0610220 (final order issued January 16, 2007) (<https://www.ftc.gov/enforcement/cases-proceedings/0610220/johnson-johnson-pfizer-inc-matter>). 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.
- Over-the-counter hydrocortisone anti-itch products. Hydrocortisone anti-itch products are topical medications used to treat minor skin irritations and inflammations. 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.
- 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.
- 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.

**Barr Pharmaceuticals Inc./Pliva**, C-4171 (final order issued December 8, 2006) (<http://www.ftc.gov/enforcement/cases-proceedings/0610217/barr-pharmaceuticals-inc-matter>). The 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 60 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.

**Watson Pharmaceuticals Inc./Andrx Corp.**, C-4172 (final order issued December 6, 2006) (<https://www.ftc.gov/enforcement/cases-proceedings/0610139/watson-pharmaceuticals-inc-andrx-corporation-matter>). The complaint alleged that Watson's acquisition of Andrx substantially lessened actual, potential, and future competition in 13 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-Novum 1/35, 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.

**Teva Pharmaceutical Industries/IVAX Corporation**, C-4155 (final 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 15 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 inflammation. 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/acetaminophen 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/acetaminophen 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/EON Labs**, C-4150, FTC File No. 0510106, 140 F.T.C. 480 (final order issued September 21, 2005) (<https://www.ftc.gov/enforcement/cases-proceedings/051-0106/novartis-ag-matter-eon-labs-inc>). 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 affect 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 than 95% 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 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**, C-4128, FTC File No. 0410083, 139 F.T.C. 49 (final order issued January 31, 2005) (<https://www.ftc.gov/enforcement/cases-proceedings/0410083/genzyme-corporation-ilex-oncology-inc-matter>). 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.

**Sanofi-Synthelabo/Aventis**, C-4112, FTC File No. 041 0031, 138 F.T.C. 478 (final order issued September 20, 2004) (<https://www.ftc.gov/enforcement/cases-proceedings/041-0031/sanofi-synthelabo-aventis-matter>). 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 anticoagulant 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 Camptosar. 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. At the time of the complaint, Sepracor planned to enter this market within nine months as a competitor to Sanofi with its product Estorra, which was licensed to Sepracor from Aventis. Under the licensing agreement, Aventis was 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 was 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**, C-4075, FTC File No 0210192, 135, F.T.C. 608 (final order issued May 27, 2003) (<https://www.ftc.gov/enforcement/cases-proceedings/021-0192/pfizer-inc-pharmacia-corporation>). 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.

- 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.
- 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 Nasteck 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.
- 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 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**, C-4068, FTC File No. 0210171, 135 F.T.C. 49 (final order issued February 3, 2003) (<https://www.ftc.gov/enforcement/cases-proceedings/0210171/baxter-international-inc-wyeth-matter>). 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 were 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 requires the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company.
- 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 requires 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 complicated 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**, C-4056, FTC File No. 0210059, 134 F.T.C. 333 (final order issued September 3, 2002) (<https://www.ftc.gov/enforcement/cases-proceedings/0210059/amgen-inc-immunex-corporation>). 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.** Neutrophil regeneration factors are used to help the immune systems of chemotherapy patients by increasing the production of two types of white blood cells. 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. The order requires that Immunex divest its Leukine product to Schering AG.
- **TNF Inhibitors.** TNF inhibitors are used to treat inflammation in patients having autoimmune diseases by preventing the binding of TNF (a cytokine that promotes inflammation) 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 inflammation 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.

**Glaxo Wellcome plc/SmithKline Beecham plc**, C-3990, FTC File No. 0010088, 131 F.T.C. 56 (final order issued January 26, 2001) (<https://www.ftc.gov/enforcement/cases-proceedings/0010088/glaxo-wellcome-plc-smithkline-beecham-plc-matter>). 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 requires 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 requires 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 requires 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 had similar products in development. The order requires 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 requires 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 requires 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 requires the divestiture of Glaxo's U.S. and Canadian Zantac trademark rights to Pfizer.

In three markets the order addresses 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 requires 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 requires 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 requires

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 (final 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 requires 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 prohibits 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 requires 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 requires 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 requires 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 OSI's costs for completing clinical trials on the drug.

**Roche Holding Ltd./Corange Limited**, C-3809, FTC File No. 9710103, 125 F.T.C. 919 (final order issued May 22, 1998) (<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**, C-3740, FTC File No. 9710009, 123 F.T.C. 1279 (final order issued May 16, 1997) (<https://www.ftc.gov/enforcement/cases-proceedings/9710009/american-home-products-corporation-matter>). 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 requires 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, the order requires American Home Products 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 obtains the approvals. The order also includes provisions protecting Schering-Plough from patent infringement lawsuits relating to the three vaccines.

**Baxter International, Inc./Immuno International**, C-3726, FTC File No. 9710002, 123 F.T.C. 904 (final order issued March 24, 1997) (<https://www.ftc.gov/enforcement/cases-proceedings/9710002/baxter-international>). 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 requires both divestiture and licensing. In the market for Factor VIII inhibitors, the order requires Baxter to divest its Autoplex product to a Commission-approved buyer within four months. The order also requires licensure of Baxter's fibrin sealant, and requires Baxter to provide the acquirer, Haemacure, with finished product for sale.

**IVAX/Zenith Laboratories**, C-3565, 119 F.T.C. 357 (final order issued March 27, 1995). 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 permits 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 requires IVAX to obtain prior Commission approval before acquiring any stock in a company that manufactures 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**, C-3557, 119 F.T.C. 217 (final order issued February 14, 1995). 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 order requires 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 also requires changing the licensing agreement for cytokines and eliminating reporting arrangements to assure that American Home Products does not obtain competitively-sensitive information.

**Dow Chemical Company, et al.**, (Darby Group Companies, Inc./Marion Merrell Dow, Inc.), C-3533, 118 F.T.C. 730 (final order issued September 23, 1994). 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 requires MMD to license dicyclomine formulations and production technology to a third-party within 12 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 requires 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**

**Sanofi/Maze Therapeutics, Inc.**, FTC File No. 2310091; Case No. 1:23-cv-13046 (administrative and federal district court complaints filed December 11, 2023; complaints dismissed December 20, 2023, and December 13, respectively). (<https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-termination-sanofis-proposed-acquisition-maze-therapeutics-pompe-disease-drug>). The complaint alleged that Sanofi's proposed acquisition of an exclusive license to Maze Therapeutics Inc.'s Pompe disease drug in development would eliminate a nascent competitor and threat to Sanofi's monopoly in the Pompe disease therapy market. Pompe disease is a debilitating and potentially fatal genetic disorder, and Sanofi is a monopoly supplier of FDA approved drugs to treat it. According to the complaint, Maze's developmental drug threatens to undermine this monopoly as the first oral medication available for Pompe disease patients, whereas Sanofi's drugs are administered via lengthy, biweekly intravenous infusions. The complaint alleged the transaction would protect Sanofi's monopoly and deny patients and doctors the benefits of competition, including lower prices and greater innovation. Additionally, the Commission filed a complaint in the U.S. District Court for the Northern District of Massachusetts on December 11, 2023, seeking a temporary restraining order and a preliminary injunction to prevent the acquisition pending the administrative proceeding.

Shortly after the complaints were filed, Sanofi announced it would terminate its agreement with Maze. The FTC and Respondents jointly moved to dismiss its federal court and administrative challenge on December 13, 2023.

**Hikma Pharmaceuticals/Custopharm, Inc.**, C-4762, FTC File No. 221-0001 (administrative complaint filed April 19, 2022; final order approved July 14, 2022) (<https://www.ftc.gov/news-events/news/press-releases/2022/07/ftc-approves-final-order-preserving-competition-development-marketing-steroid-injectable-drug>). The complaint alleged that Hikma Pharmaceuticals' \$375 million acquisition of Custopharm, Inc. would lessen competition for generic corticosteroid drug triamcinolone acetonide (TCA). Hikma Pharmaceuticals is a multinational pharmaceutical company that manufactures branded and generic products and has a TCA product in development. Custopharm develops generic injectable drugs, and its TCA product was recently approved by the FDA.



The final consent order requires Custopharm's parent company to retain Custopharm's TCA assets and transfer them to another subsidiary, Long Grove Pharmaceuticals, LLC. Long Grove is a specialty drug development company that focuses on complex generic products. Long Grove is required to maintain the competitive viability of the retained assets going forward. The order also requires Hikma to seek the Commission's approval for future TCA-related acquisitions.

**ANI Pharmaceuticals, Inc./Novitium Pharma LLC**, C-4754, FTC File No. 211-0101, (final order approved January 12, 2022) (<https://www.ftc.gov/news-events/press-releases/2022/01/ftc-approves-final-order-requiring-generic-drug-marketers-ani>). The complaint alleged that ANI's proposed acquisition of Novitium violates the federal antitrust laws by reducing competition in the U.S. markets for (1) generic sulfamethoxazole-trimethoprim oral suspension tablets ("SMX-TMP oral-suspension tablets") and (2) generic dexamethasone tablets. SMX-TMP oral-suspension tablets are used to treat various infections, including ear infections, urinary tract infections, and bronchitis. Dexamethasone tablets are an oral steroid product used to treat inflammation associated with various conditions, including certain types of arthritis, allergic reactions, skin diseases, and breathing problems.

On January 12, 2022, the Federal Trade Commission settled the matter. The settlement requires ANI and Novitium to divest ANI's rights and assets to generic SMX-TMP oral-suspension tablets and dexamethasone tablets to a competitor Prasco, LLC. The settlement also contains a prior approval provision that gives the Commission notice and approval rights for future related acquisitions in these markets.

**Bristol-Myers Squibb Company/Celgene Corporation**, C-4690, FTC File No. 191-0061, (complaint filed November 15, 2019; final order issued January 13, 2020; modification of settlement approved November 12, 2021) (<https://www.ftc.gov/news-events/press-releases/2021/11/ftc-approves-modifications-bristol-meyers-squibb-divestiture>). The complaint charged that Bristol-Myers Squibb's (BMS) proposed \$74 billion acquisition of Celgene would harm consumers in the U.S. market for oral products to treat moderate-to-severe psoriasis. BMS has a pipeline product under development that is considered the most advanced oral treatment for moderate-to-severe psoriasis. According to the complaint, BMS's pipeline product will likely be the next entrant into the market and would compete directly with Celgene's Otezla product.

Psoriasis is a chronic skin disease caused by an overactive immune system. The complaint alleged that the acquisition would substantially lessen competition and tend to create a monopoly by eliminating future competition between BMS and Celgene in developing, manufacturing, and selling oral products to treat moderate-to-severe psoriasis in the United States. New competitors in this market would face lengthy delays for both drug development and FDA approval. As a result, entry into this market would not be timely, likely, or sufficient to deter the anticompetitive effects of the acquisition.

Following a public comment period, the FTC approved a final order on January 13, 2020, settling all charges in the matter. Under the order, Bristol-Myers Squibb will divest Celgene's Otezla product to Amgen, Inc. for \$13.4 billion. Amgen, a California-based pharmaceutical and biologic company, has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the challenged acquisition.

On November 12, 2021, the Federal Trade Commission approved certain modifications to the settlement. The modifications relate to confidential settlement provisions and are necessary to ensure that Amgen remains a viable competitor.

**Pfizer Inc./Mylan N.V.**, C-4727, FTC File No. 1910182 (proposed consent order issued October 30, 2020; final order issued January 28, 2021) (<https://www.ftc.gov/news-events/press-releases/2021/01/ftc-approves-final-order-imposing-conditions-combination-pfizer>). The Federal Trade Commission's complaint alleged that a proposed combination of Upjohn Inc. (a division of Pfizer Inc.) and Mylan N.V. would harm current or future competition in ten generic drug markets and violate federal antitrust law. The complaint also alleged that the proposed combination would delay or eliminate a likely entrant in three product markets, reducing the likelihood that prices would decrease in the future.

On January 28, 2021, the Commission approved a final order settling the charges. The settlement seeks to remedy competitive concerns in seven generic pharmaceutical markets by requiring the parties Pfizer Inc., Upjohn Inc., Mylan N.V., and Viartis Inc. (the newly formed entity) to divest to Prasco, LLC the rights and assets related to Upjohn's amlodipine besylate/atorvastatin calcium tablets, phenytoin chewable tablets, prazosin HCl capsules, spironolactone HCTZ tablets, gatifloxacin ophthalmic solution, and medroxyprogesterone acetate injectable solution. The parties must also divest the rights and assets related to Mylan's eplerenone tablets.

The final order also requires prior Commission approval before Upjohn, Mylan, or Viartis may gain an interest in or exercise control over any third party's rights to levothyroxine sodium tablets, sucralfate tablets, and varenicline tartrate tablets.

Commission staff and the staff of antitrust agencies in Australia, Canada, the European Union, and New Zealand worked cooperatively to analyze the proposed transaction and potential remedies.

**Roche Holding/Spark Therapeutics**, FTC File No. 191-0086 (Investigation closed December 16, 2019), <https://www.ftc.gov/news-events/press-releases/2019/12/federal-trade-commission-closes-investigation-roche-holding-ags>. The Federal Trade Commission has closed its investigation into Roche Holding AG's proposed acquisition of Spark Therapeutics, Inc. According to a Commission closing statement, after an exhaustive 10-month investigation into whether the merger would lessen potential competition in any market related to hemophilia A therapies sold in the United States, the evidence did not indicate that Roche would have the incentive to delay or terminate Spark's developmental effort for its hemophilia A gene therapy, or that the acquisition would affect Roche's incentives regarding its hemophilia treatment drug, Hemlibra.

**Baxter International Inc./Claris Lifesciences Limited and Arjun Handa**, C-4620, FTC File No. 1710052 (final order issued August 28, 2017) <https://www.ftc.gov/enforcement/cases-proceedings/171-0052/baxter-international-inc-claris-lifesciences-limited-arjun>. The FTC issued an administrative complaint on July 20, 2017 and issued a final order on August 28, 2017. The complaint alleged that Baxter's proposed acquisition of Claris's injectable drugs business would reduce competition for the antifungal agent fluconazole in saline intravenous bags, which is used to treat fungal and yeast infections. The complaint further alleged that the acquisition would also

reduce imminent, future competition in the market for intravenous milrinone, which dilates the blood vessels, lowers blood pressure and allows blood to flow more easily through the cardiovascular system. Used as a short-term treatment for life-threatening heart failure, intravenous milrinone is currently sold in the United States by three companies – Baxter, Hikma and Pfizer. Claris was expected to enter this market shortly, once its pending application at the FDA was approved. The order requires the parties to divest all of Claris’s rights to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to New Jersey-based pharmaceutical company Renaissance Lakewood LLC. The order also requires Baxter to supply Renaissance with fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags for up to five years while transferring the manufacturing technology to Renaissance or its contract manufacturing designee. Baxter is also required to assist Renaissance in establishing its manufacturing capabilities and securing the necessary FDA approvals. If the Commission determines that Renaissance is not an acceptable acquirer, or that the divestiture is not carried out in an acceptable way, the parties are required to unwind the sale of rights to Renaissance and divest the products to a Commission-approved acquirer within six months of the date the order becomes final.

**C.H. Boehringer Sohn AG & KG/Sanofi** (See Section IV A for citation and annotation.)

**Mylan N.V./Meda AB** (See Section IV A for citation and annotation.)

**Teva Pharmaceutical Industries Ltd./Allergan PLC** (See Section IV A for citation and annotation.)

**Hikma Pharmaceuticals/Boehringer Ingelheim Corporation (Roxane Laboratories, Inc.)** (See Section IV A for citation and annotation.)

**Lupin Ltd./Gavis Pharmaceuticals LLC and Novel Laboratories, Inc.** (See Section IV A for citation and annotation.)

**Hikma Pharmaceuticals PLC/ C.H. Boehringer Sohn AG & Co. KG (Ben Venue Laboratories, Inc.)**, C-4572, FTC File No. 1510044 (final order issued March 28, 2016) (<https://www.ftc.gov/news-events/press-releases/2016/02/ftc-requires-drug-marketer-hikma-pharmaceuticals-plc-divest>). The complaint alleged that the proposed acquisition by Hikma Pharmaceuticals PLC of certain assets of Ben Venue Laboratories Inc., a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG, would lessen competition by eliminating future competition between Hikma and the Boehringer assets and reducing the number of generic competitors in five generic injectable pharmaceutical markets. Thus, the complaint charged, the proposed acquisition would (a) increase the likelihood that the combined entity would forego or delay the launch of these products, and (b) increase the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

- Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. At the time of the complaint, three firms, including Boehringer, had approved Abbreviated New Drug Applications for this drug. Only two firms currently

supplied acyclovir sodium injection to the market. Hikma and one other firm was likely to enter the market in the near future. Thus, according to the complaint, the proposed acquisition would reduce the number of likely future suppliers of acyclovir sodium injection from five to four.

- Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. At the time of the complaint, there were four firms, including Hikma and Boehringer, that had FDA-approved ANDAs for diltiazem hydrochloride injection, but only Hikma, and two other firms were current suppliers in the market. The complaint alleged that no other firms were likely to enter the market in the near future. Thus, the proposed acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.
- Famotidine injection treats ulcers and gastroesophageal reflux disease. At the time of the complaint, three firms, including Hikma, sold the vial presentation of famotidine injection. Boehringer had an FDA-approved ANDA for famotidine injection vials, but had no sales during the year prior to the proposed acquisition. No other companies had FDA-approved ANDAs for famotidine injection vials. The complaint charged that the proposed acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.
- Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. According to the complaint, Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. From that point until the complaint was filed, Heritage Pharmaceuticals Inc. had assumed all sales of prochlorperazine edisylate injection. Hikma was the only other company that had an FDA-approved ANDA for prochlorperazine edisylate injection, but it was not supplying the market. Another firm had prochlorperazine edisylate injection in its development pipeline and anticipated achieving FDA approval of its ANDA in the near future. Thus, the proposed acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.
- Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. At the time of the complaint, there were two firms, including Hikma, that supplied valproate sodium injection in the market. Boehringer had an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm had valproate sodium injection in its development pipeline and anticipated achieving FDA approval of its ANDA in the near future. Thus, the proposed acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

The order requires Hikma to divest to Amphastar Pharmaceuticals, Inc. the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection.

**Pfizer Inc./Hospira, Inc.** (See Section IV A for citation and annotation.)

**Impax Labs. Inc./CorePharma, L.L.C.**, C-4511, FTC File No. 1510011 (final order issued April 22, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/151-0011-c-4511/impax-laboratories-inc-et-al-matter>). The complaint alleged that Impax Laboratories, Inc.'s proposed acquisition of Tower Holdings, Inc., Tower's subsidiary, CorePharma, L.L.C., and Lineage Therapeutics Inc. from Roundtable Healthcare Partners II, L.P. would eliminate future competition between Impax and CorePharma in the market for generic 5 mg pilocarpine hydrochloride tablets, used to treat dry mouth, and generic ursodiol tablets, used to treat biliary cirrhosis. At the time of the complaint, the market for generic 5mg pilocarpine hydrochloride tablets was highly concentrated with only two suppliers. The complaint alleged that CorePharma and Impax each held an approved Abbreviated New Drug Application and were the only suppliers expected to enter the market in the near future. CorePharma was also among a limited number of firms with an ANDA under review for generic ursodiol tablets and the next likely entrant in the generic ursodiol tablet market. As a result, the complaint charged that the proposed acquisition would significantly reduce future competition, including a likely reduction in the number of future generic ursodiol tablet suppliers from five to four. The order requires the companies to divest CorePharma's rights and assets to generic pilocarpine tablets and generic ursodiol tablets to the Perrigo Company plc.

**Novartis, AG**, C-4510, FTC File No. 1410141 (final order issued April 7, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0141-c-4510-c-4498/novartis-ag-matter-glaxosmithkline>). The complaint charged that Novartis AG's proposed acquisition of GlaxoSmithKline, PLC's (GSK) marketed oncology products, BRAF and MEK inhibitors used to treat cancer, would eliminate substantial future competition between GSK and Novartis. The complaint alleged that GSK was one of two companies with a BRAF inhibitor on the market, while Novartis was the only other firm likely to begin competing with a BRAF inhibitor in the near future. The complaint alleged that GSK was the only company with a MEK inhibitor on the market, while Novartis was one of small number of companies with a MEK inhibitor in late-stage development. Finally, the complaint alleged that GSK was the only company with a BRAF/MEK combination product to treat melanoma on the market, while Novartis was one of only two companies likely to compete with a combination product in the near future. The order requires Novartis to divest its BRAF and MEK inhibitor drugs to Array BioPharma, Inc.

**Sun Pharmaceutical Industries Ltd./Ranbaxy Laboratories Ltd.**, C-4506, FTC File No. 1410134 (final order issued March 18, 2015) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0134/sun-pharmaceutical-industries-ltd-et-al-matter>). The complaint alleged that the proposed acquisition by Sun Pharmaceutical Industries Ltd. of Ranbaxy Laboratories Ltd. would substantially eliminate future competition in the market for various dosages of generic minocycline tablets, used to treat an array of bacterial infections, including pneumonia, acne, and urinary tract infections. According to the complaint, Ranbaxy was one of only three U.S. suppliers, while Sun was one of a limited number of firms likely to develop generic minocycline tablets. The complaint charged that the combined entity likely would forego or delay the launch of Sun's products reducing the price competition that would have resulted from Sun's entry. The order requires the parties to divest Ranbaxy's assets and licenses in generic minocycline tablets to Torrent Pharmaceuticals Ltd. The order also requires Sun and Ranbaxy to sell Ranbaxy's generic minocycline capsule assets to Torrent to enable Torrent to achieve regulatory approval for its minocycline tablets product as quickly as Ranbaxy would have been able to in the absence of the deal.

**Akorn, Inc./VersaPharm, Inc.**, C-4479, FTC File No. 1410162 (final order issued September 16, 2014) (<https://www.ftc.gov/enforcement/cases-proceedings/141-0162/akorn-inc-matter>). The complaint alleged that the proposed acquisition by Akorn, Inc. of VersaPharm, Inc. and its parent company, VPI Holdings Corp., would reduce future competition for generic injectable rifampin, an antibacterial medication used as a first-line treatment to kill or prevent the growth of tuberculosis. The complaint stated that VersaPharm was one of three generic drug companies with an approved Abbreviated New Drug Application for rifampin. At the time of the complaint, Akorn was one of a limited number of firms awaiting Food and Drug Administration approval for a generic rifampin product, which was expected in the foreseeable future. As a result, the complaint charged that the proposed acquisition would significantly reduce future competition, including price competition, by increasing the likelihood that the combined entity would forego or delay the launch of Akorn's generic injectable rifampin. The order requires Akorn to divest its ANDA for generic injectable rifampin, pending before the FDA, to Watson Laboratories, Inc.

**Actavis PLC/Forest Laboratories, Inc.** (See Section IV A for citation and annotation.)

**Akorn, Inc./Hi-Tech Pharmacal, Inc.** (See Section IV A for citation and annotation.)

**Endo Health Solutions, Inc./Boca Pharmacal, LLC** (See Section IV A for citation and annotation.)

**Mylan, Inc./Strides Arcolab Ltd.** (See Section IV A for citation and annotation.)

**Actavis, Inc./Warner Chilcott plc** (See Section IV A for citation and annotation.)

**Watson Pharmaceuticals Inc./Actavis, Inc.** (See Section IV A for citation and annotation.)

**Novartis, AG/Fougera Holdings, Inc.** (See Section IV A for citation and annotation.)

**Perrigo Company/Paddock Laboratories, Inc.** (See Section IV A for citation and annotation.)

**Watson Pharmaceuticals, Inc./Robin Hood Holdings (Arrow)**, C-4276, FTC File No. 0910116 (final order issued January 7, 2010) (<https://www.ftc.gov/enforcement/cases-proceedings/091-0116/watson-pharmaceuticals-inc-corporation-robin-hood-holdings>). The Commission's complaint challenged Watson's proposed \$1.75 billion acquisition of Arrow. The complaint charged 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. At the time of the complaint, Arrow was one of only three suppliers of generic cabergoline in the \$44.8 million U.S. market. Watson had FDA approval to sell generic cabergoline, and was 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 was one of only two suppliers of generic dronabinol in the \$74.4 million U.S. market. Arrow's subsidiary, Resolution Chemicals Ltd., was developing a generic dronabinol



product, and was one of a limited number of firms capable of developing generic dronabinol and marketing it in a manner that was timely and sufficient to have a competitive impact. The proposed acquisition would eliminate the likely entry of the Arrow/Resolution competing product.

The complaint charged 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 would pay higher prices for these generic products. 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.

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

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

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

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

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

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

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

**Allergan Inc./Inamed Corp.**, C-4156, FTC File No. 0610031 (final order issued April 17, 2006) (<https://www.ftc.gov/enforcement/cases-proceedings/061-0031/allergan-inc-inamed-corporation-matter>). 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 Ipsen 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 IV A for citation and annotation.)

**Cephalon, Inc./Cima Labs Inc.**, C-4121, FTC File No. 0410025, 138 F.T.C. 583 (final order issued September 20, 2004) (<https://www.ftc.gov/enforcement/cases-proceedings/0410025/cephalon-inc-cima-labs-inc>). 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 IV A for citation and annotation.)

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

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

**Glaxo Wellcome plc/SmithKline Beecham plc** (See Section IV A for citation and annotation.)

**Hoechst AG/Rhone-Poulenc**, C-3919, FTC File No. 9910071 (final 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 requires 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/Astra**, C-3880, FTC File No. 9910089, 127 F.T.C. 874 (final order issued June 7, 1999) (<https://www.ftc.gov/enforcement/cases-proceedings/9910089/zeneca-group-pl>). 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 requires 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 consist principally of intellectual property and know-how, and include all of the applicable patents, trademarks, copyrights, technical information, and market research relating to levobupivacaine. During a transitional period, Zeneca is required to continue carrying out certain ongoing activities relating to the commercialization of levobupivacaine, including manufacturing, regulatory, clinical, development, and marketing activities. Zeneca is also required to divest its approximately 3% investment interest in Chiroscience.

**Baxter International, Inc./Immuno International** (See Section IV A for citation and annotation.)

**Hoechst AG/Marion Merrill Dow**, C-3629, FTC File No. 9510090, 120 F.T.C. 1010 (final order issued December 5, 1995) (<https://www.ftc.gov/news-events/press-releases/1995/12/ftc-gives-final-approval-consent-agreement-hoechst-ag>). 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 requires 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 is 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 is required to divest one of the two drugs. In each market, Hoechst is required to divest either the current line of business or the potential new product to a Commission-approved buyer that will 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 IV A for citation and annotation.)

### C. Innovation Market Mergers

**Novartis AG/GlaxoSmithKline, PLC** (See Section IV A for citation and annotation)

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

**Baxter International, Inc./Immuno International** (See Section IV A for citation and annotation.)

**Ciba-Geigy, Ltd./Sandoz**, C-3725, FTC File No. 9610055 (final order issued March 24, 1997) (<https://www.ftc.gov/enforcement/cases-proceedings/961-0055/ciba-geigy-limited-sandoz-ltd-novartis-ag-et-al-matter>). 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 centers on the intellectual property rights. The new company, Novartis, is 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 can receive an up-front payment of \$10,000 and royalties of one to three percent of net sales. Novartis also is 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 can request from the licensee consideration in the form of royalties and/or an equivalent cross-license. Further, the merged company cannot acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy.

**The Upjohn Co./Pharmacia Aktiebolag**, C-3638, FTC File No. 95101, 121 F.T.C. 44 (final order issued February 8, 1996) (<https://www.ftc.gov/enforcement/cases-proceedings/951-0140c-3638/upjohn-company-pharmacia-aktiebolag-matter>). 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 requires the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.

**Glaxo PLC/Burroughs Wellcome**, C-3586, FTC File No. 9510054, 119 F.T.C. 815 (final order issued June 14, 1995) (<https://www.ftc.gov/news-events/press-releases/1995/06/glaxo-plc>). 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 requires the combined firm to divest Wellcome's assets related to the research and development of the migraine remedy. Among those assets are patents, technology, manufacturing information, testing data, research materials, and customer lists. The assets also include inventory needed to complete all trials and studies required to obtain FDA approval.

#### **D. Other Theories of Harm**

**Amgen Inc./Horizon Therapeutics plc.**, FTC File No. 2310037, Case No. 1:23-cv-03053 (amended complaint filed June 22, 2023; final order approved December 14, 2023) (<https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-approves-final-order-settling-horizon-therapeutics-acquisition-challenge>). In May 2023, the Federal Trade Commission, joined by the states of California, Illinois, Minnesota, New York, Washington, and Wisconsin, sued to block pharmaceutical company Amgen Inc. from acquiring Horizon Therapeutics plc. Amgen is one of the world's largest pharmaceutical manufacturers with a portfolio of 27 approved drugs,

and Horizon is a biotechnology company focused on medicines treating rare, auto immune, and severe inflammatory diseases.

The FTC alleged that the transaction would enable Amgen to leverage rebates from various blockbuster drugs in its portfolio to pressure payers and pharmacy benefit managers into foreclosing competition to Tepezza or Krystexxa, Horizon's medications used to treat thyroid eye disease and chronic refractory gout, respectively, and which have little to no direct competition. This could have deprived patients, doctors, and health plans from the benefits of competition and access to critical new treatment options for thyroid eye disease and chronic refractory gout.

On September 1, 2023, the FTC, participating states, and the parties agreed to a proposed Consent Order resolving the allegations in the Commission's complaint, and the Commission finalized the order on December 14, 2023, after a public comment period. Under the final Consent Order, Amgen is prohibited from bundling an Amgen product with either Tepezza or Krystexxa. In addition, Amgen may not condition any product rebate or contract term related to an Amgen product on the sale or positioning of either one of these drugs. Amgen also is barred from using any product rebate or contract term to exclude or disadvantage any product that would compete with Tepezza or Krystexxa. Additionally, Amgen must seek FTC approval prior to acquiring any products or businesses that treat either thyroid eye disease or chronic refractory grout through 2032 and notify the states if it is seeking Commission approval.

## **V. MERGERS INVOLVING PHARMACEUTICAL DISTRIBUTION**

### **A. Horizontal Mergers between Direct Competitors**

**Omnicare Inc./PharMerica Corporation**, C-9352, FTC File No. 1110239 (complaint dismissed February 22, 2012) (<http://www.ftc.gov/enforcement/cases-proceedings/111-0239/omnicare-inc-corporation-matter>). In its complaint the FTC charged that Omnicare's hostile acquisition of PharMerica Corporation would combine the two largest U.S. long-term care pharmacies and harm competition by enabling Omnicare to raise the price of drugs for Medicare Part D consumers and others.

Omnicare operates approximately 204 long-term care pharmacies in 44 states, and PharMerica owns and operates 97 long-term care pharmacies in 43 states. The complaint states that the acquisition would significantly increase Omnicare's already substantial bargaining leverage by increasing dramatically the number of skilled nursing facilities, known as SNFs, that receive long-term care pharmacy services from the company. The combined firm would serve approximately 57% of all licensed SNF beds in the country. Because of its substantial market share, the combined firm would be an indispensable source of long-term pharmacy services for Medicare Part D prescription drug plans, which are responsible for providing subsidized prescription drug benefit coverage for most SNF residents and other Medicare beneficiaries. The Centers for Medicare & Medicaid Services of the Department of Health and Human Services concluded that the proposed acquisition is likely to result in higher reimbursement rates and thereby increase the cost to CMS (and therefore to the U.S. government and U.S. taxpayers) as well as to any individuals paying out-of-pocket costs in connection with long-term care pharmacy services.



Long-term care pharmacies do not provide medications directly to “walk-in” consumers from nearby homes. They work with SNFs and other institutional providers to arrange for the delivery and administration of prescription medications to the SNF’s residents. Because most SNF residents need help with ordering, delivery and administration of their drugs, a majority of them obtain prescription drug coverage from a Part D prescription plan. CMS requires Part D plans to provide SNF residents with “convenient access” to a network of long-term care pharmacies, such as Omnicare and PharMerica. This requirement ensures that SNF residents can get their prescription drugs from a long-term pharmacy that contracts with the residents’ chosen Part D health plan. If a health plan cannot provide its beneficiaries with “convenient access” to long-term care pharmacies, it runs the risk of being barred from offering Medicare Part D health plans.

According to the complaint, Omnicare has been able to use its size to exert bargaining leverage over Part D health plans by threatening to terminate contracts if its terms are not met. A combined Omnicare/PharMerica would have the unique ability to exercise even greater bargaining power to raise prices of drugs to Part D health plans. Losing contracts with the combined firm would put the Part D health plans at serious risk of failing to meet CMS’s “convenient access” standard. This increased risk would provide the combined firm with an anticompetitive advantage in negotiating prices it charges Part D health plans for long-term care pharmacy services.

The case was scheduled to be heard before an administrative law judge at the FTC in June 2012. However, on February 23, 2012, the Commission dismissed the complaint because Omnicare announced that it had allowed its tender offer to acquire the outstanding shares of PharMerica to expire.

**Cardinal Health, Inc./Biotech Pharmacy Inc., et.al.**, FTC File No. 0910136 (final order issued October 21, 2011) (<https://www.ftc.gov/enforcement/cases-proceedings/0910136/cardinal-health-inc-matter>). The complaint charged that the purchase by Cardinal Health, Inc. of nuclear pharmacies from Biotech Pharmacy Inc., *et al.* reduced competition for low-energy radiopharmaceuticals in three cities. The Commission 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 then held a low-energy radiopharmaceuticals monopoly in Albuquerque. In El Paso, although another nuclear pharmacy opened November 2010, Cardinal still held 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, a large market share. The complaint alleged that Cardinal’s acquisition of Biotech’s nuclear pharmacies would likely

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 requires 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 require 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.

**Rite Aid Corp./The Jean Coutu Group, Inc.**, C-4191 (final order issued June 1, 2007) (<https://www.ftc.gov/enforcement/cases-proceedings/0610257/rite-aid-corporation-jean-coutu-group-pjc-inc-matter>). 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 23 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 23 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.

**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.

**J.C. Penney Company/Eckerd Corporation/Rite Aid**, C-3721, C-3722, FTC File Nos. 9710017, 9710016, 123 F.T.C. 778, 795 (final orders issued February 28, 1997) (<https://www.ftc.gov/enforcement/cases-proceedings/971-0017-971-0016/jc-penney-company-inc-thrift-drug-inc-matter>). 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 13 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 requires 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 bars J.C. Penny from acquiring the 127 stores in North and South Carolina until a divestiture agreement approved by the Commission is in place, and in addition, allows the Commission to appoint a trustee to divest the other 63 drug stores acquired from Rite Aid if the divestitures of the 127 stores are not completed on time. The order also requires that the stores be divested to a single pharmacy chain to ensure that the buyer can maintain the size and resources necessary to serve as a competitive pharmacy chain in a PBM's pharmacy network.

**CVS Corporation/Revco**, C-3762, FTC File No. 9710060, 124 F.T.C. 161 (final order issued August 13, 1997); Civil Action No. 1:98CV0775 (D.D.C. filed March 26, 1998)

(<https://www.ftc.gov/enforcement/cases-proceedings/971-0060/cvs-corporation-revco-ds-inc>).

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 requires 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 allows 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 are not completed three months after the order is 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. 9610020 (preliminary injunction authorized April 17, 1996) (<https://www.ftc.gov/news-events/press-releases/1998/02/riteaid-pay-900000-civil-penalties-failure-divest-three-drug>). 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. 9510120 (closing letter sent May 31, 1996) (<https://www.ftc.gov/news-events/press-releases/1996/06/ftc-closes-investigation-rite-aid-acquisition-maxi-drug-maine>). 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.

**Rite Aid Corporation/LaVerdiere's Enterprises, Inc.**, C-3546, 118 F.T.C. 1206 (final order issued December 15, 1994), Civil Action No. 1:98CV0484 (D.D.C. filed February 27, 1998), 125 F.T.C. 846 (1998) (modifying order) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-118>). 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 12 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.**, (TCH/Payless), C-3519, 118 F.T.C. 368 (final order issued August 16, 1994) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-118>). 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 requires 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.

**Revco D.S. Inc./Hook-SupeRx**, C-3540, 118 F.T.C. 1018 (final order issued October 31, 1994) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-118>).

118). 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.

## **B. Vertical Mergers**

**Merck & Co., Inc./Medco**, C-3853, FTC File No. 9510097, 127 F.T.C. 156 (final order issued February 18, 1999) (<https://www.ftc.gov/enforcement/cases-proceedings/9510097/merck-co-inc-merck-medco-managed-care-llc>). 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**, C-3594, 120 F.T.C. 243 (final order issued July 28, 1985) (<https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-120>); 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.

## **VI. INDUSTRY GUIDANCE STATEMENTS INVOLVING PHARMACEUTICAL PRODUCTS AND DISTRIBUTION**

### **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 website at <https://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 new regulations, effective August 18, 2003, to modify in part its regulations concerning Orange Book listings.

## **C. FTC Amendments to the Premerger Notification Rules Related to the Transfer of Exclusive Patent Rights in the Pharmaceutical Industry**

On November 6, 2013, the Federal Trade Commission, with the concurrence of the Assistant Attorney General, Antitrust Division, Department of Justice, issued [changes to the premerger notification rules](#) (FTC File No. P98316) that require companies in the pharmaceutical industry to report certain proposed acquisitions of exclusive patent rights to the Commission and the Department of Justice for [antitrust review](#). The revised rules clarify when a transfer of exclusive rights to a patent in the pharmaceutical industry results in a potentially reportable asset acquisition under the Hart Scott Rodino (HSR) Act.

The HSR Act established the federal premerger notification program, which provides the Commission and the Department of Justice with information about certain large mergers and acquisitions before they occur. The Commission administers the premerger notification program and ensures compliance with the HSR Rules, which determine which transactions companies need to report.

In response to the Notice of Proposed Rulemaking, the FTC received [three public comments](#), including one from the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association that represents biopharmaceutical researchers and biotechnology companies. The rules became effective on December 16, 2013.

PhRMA brought an action in the U.S. District Court for the District of Columbia to set aside the revised rules issued by the Commission. On May 30, 2014, the district court upheld the Commission's authority to issue the rules (Civil Case No. 13-1974 (BAH)) (Pharm. Research & Mfrs. of Am. v. FTC, 2014 U.S. Dist. LEXIS 73822 (D.D.C. May 30, 2014)). On June 9, 2015, the United States Court of Appeals for the District of Columbia Circuit affirmed the district court's decision. (<http://www.ftc.gov/enforcement/cases-proceedings/p072104/phrma-v-ftc>).

## **D. 2004 Report: Improving Health Care: A Dose of Competition**

In July 2004, the Federal Trade Commission and Department of Justice issued a joint report to inform consumers, businesses, and policy-makers on a range of issues affecting the



cost, quality, and accessibility of health care. The report is based on 27 days of FTC/DOJ Joint Hearings on Health Care and Competition Law and Policy, held from February through October 2003; an FTC-sponsored workshop in September 2002; and independent research. On July 20, 2023, the Commission issued a statement cautioning against reliance on the 2004 Report.

#### **E. FTC Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book**

In September 2023, the Federal Trade Commission issued a policy statement, supported by the U.S. Food and Drug Administration (FDA), warning pharmaceutical companies that make and sell brand-name drugs that they could face legal action if they improperly list patents in the FDA's catalog of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." The FDA's Orange Book is a list of drug products approved by the agency as safe and effective, and listing certain types of brand drug patents is a statutory requirement. When a brand pharmaceutical company lists a patent in the Orange Book, it may lead to a statutory stay that blocks the introduction of competing drug products for up to 30 months, including lower-cost generic alternatives.

Listing patents in the Orange Book can negatively affect competitive conditions if those listings are improper, as defined by law. As described in the policy statement, improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives. Accordingly, the policy statement emphasizes that the "FTC will continue to use all its tools to halt unlawful business practices that contribute to high drug prices," which includes using FDA's regulatory process for disputing a brand company's patent listing and scrutinizing improper listings as potential unfair methods of competition in violation of Section 5 of the FTC Act.

### **VII. AMICUS BRIEFS INVOLVING PHARMACEUTICAL PRODUCTS AND DISTRIBUTION**

#### **A. Reverse Payment**

**In re Bystolic Antitrust Litigation, Brief of Federal Trade Commission as *Amicus Curiae* in Support of Plaintiffs-Appellants**, No. 23-410 (2d Cir. June 20, 2023) (<https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-files-amicus-brief-bystolic-antitrust-litigation-supporting-competition-hypertension-drug-market>). The case relates to Forest Laboratories Inc. and six generic drug manufacturers' alleged efforts to delay competition with Bystolic, Forest's brand-name high blood pressure drug. The plaintiffs, who are purchasers of Bystolic, allege that Forest used the pretext of contemporaneous business deals to mask large and unjustified reverse payments to six would-be generic rivals. Under these deals, the generic rivals agreed to stop challenging Forest's patents and to refrain from selling generic versions of Bystolic for at least eight years. The district court dismissed the complaint, relying on its own hypothesized explanations for the side business deals to conclude that plaintiffs had not sufficiently alleged unjustified reverse payments.

On appeal to the Second Circuit, the FTC filed an amicus brief in support of the plaintiff-appellants, urging the court to reverse the dismissal and recognize that the large reverse

payments Forest made to the generic companies may violate the antitrust laws. The FTC’s brief explains that plaintiffs challenging a reverse payment settlement need only plead market power and a factual basis for inferring the existence of a large and unjustified reverse payment—a standard plaintiffs met. Under this approach, the court should have placed the burden principally on Forest and its co-defendants to justify the reverse payments. Instead, however, the court erroneously required plaintiffs to anticipate and preempt possible justifications prior to discovery. The brief also explains how the district court improperly found facts and drew inferences against the plaintiffs, unfairly faulted them for not producing evidence at the pleading stage, and failed to assess the allegations of the complaint holistically.

**UFCW Local 1500 Welfare Fund, et al. v. AbbVie, Inc., Brief of Amicus Curiae the Federal Trade Commission in Support of No Party**, No. 20-2402 (7th Cir. Oct. 13, 2020)

(<https://www.ftc.gov/policy/advocacy/amicus-briefs/2020/10/ufcw-local-1500-welfare-fund-et-al-v-abbvie-inc-et-al>). This case involves, among other things, settlements of patent litigation between defendants AbbVie, seller of the anti-inflammatory biologic drug Humira, and four makers of biosimilar versions of Humira: Amgen, Samsung Bioepis, Sandoz, and Fresenius Kabi. Plaintiffs in this private action alleged that AbbVie settled its patent disputes with the potential biosimilar competitors by paying them to stop challenging AbbVie’s patents and to refrain from selling their biosimilar products in the United States until at least 2023. The alleged payment consisted of AbbVie’s agreement to grant the biosimilars European patent licenses beginning in 2018. On June 8, 2020, the district court dismissed the complaint. The court concluded that the settlements were not unlawful under the Supreme Court’s decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), because in both Europe and the United States the settlements permitted “early” biosimilar competition—that is, biosimilars were licensed to enter both markets before AbbVie’s patents were slated to expire. The court further opined that upholding the challenged settlements would encourage litigants to settle worldwide patent disputes.

On appeal to the Seventh Circuit, the Commission filed an *amicus* brief on October 13, 2020. The brief took no position on the merits of the case. Instead, it argued that the district court’s analysis is inconsistent with *Actavis* in two critical ways. First, the Commission argued that the court placed undue weight on the fact that the challenged settlements allowed “early” competition before AbbVie’s patents expired. That approach conflicts with *Actavis*, which overruled a line of decisions holding that a reverse-payment settlement is exempt from antitrust scrutiny solely because it involves entry before patent expiration. The proper inquiry under *Actavis* is (1) whether the parties settled with a reverse payment to eliminate the risk of competition, and (2) whether the payment has a legitimate justification apart from the parties’ desire to share monopoly profits. Second, the Commission argued that the court erred to the extent it based dismissal on the public policy favoring settlement. *Actavis* held that policies favoring litigation settlement should not determine the outcome of a reverse-payment case.

**In re: Wellbutrin XL Antitrust Litigation, Federal Trade Commission’s Brief as Amicus Curiae**, Case no. 2:08-cv-2431, Case no. 2:08-cv-2433 (E.D. Pa. September 26, 2013); **Brief of Federal Trade Commission as Amicus Curiae in Support of No Party**, Nos. 15-3559, 15-3591, 15-3681 & 15-3682 (3d Cir. March 11, 2016). The case involves an alleged reverse-payment agreement involving brand-name drug manufacturer GlaxoSmithKline plc (GSK) and generic pharmaceutical companies Teva Pharmaceuticals and Anchen Pharmaceuticals. The plaintiffs in this private action alleged that the generic companies agreed to delay introduction of

a generic version of GSK's blockbuster antidepressant drug Wellbutrin XL in return for GSK's agreement to refrain from marketing an authorized generic version of Wellbutrin XL. In the district court proceedings, the FTC submitted an amicus brief arguing that the court should reject GSK's argument that the antitrust analysis required by the Supreme Court in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), is limited to reverse payments that take the form of cash. The district court brief also described the process for government review of pharmaceutical patent settlement agreements, explaining that a lack of action on a filed agreement does not signify approval or a lack of antitrust concern.

([https://www.ftc.gov/system/files/documents/amicus\\_briefs/wellbutrin-xl-antitrust-litigation-re/130926wellbutrinbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/wellbutrin-xl-antitrust-litigation-re/130926wellbutrinbrief.pdf)). The district court denied the Commission's motion for leave to participate as an *amicus curiae*, but subsequently rejected GSK's narrow reading of *Actavis*.

The FTC filed an *amicus* brief in the court of appeals in March 2016, addressing the district court's decision granting summary judgment in favor of the defendants.

([https://www.ftc.gov/system/files/documents/amicus\\_briefs/re-wellbutrin-antitrust-litigation/160311wellbutrinbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/re-wellbutrin-antitrust-litigation/160311wellbutrinbrief.pdf)). The Commission identified four legal errors in the district court's antitrust analysis: (1) that the district court erroneously concluded that a reverse-payment settlement that allowed the underlying patent litigation to continue, while the brand-name drugmaker paid the generic drugmaker not to enter at risk during the pendency of the litigation, did not raise the anticompetitive harm identified by the Supreme Court in *Actavis*; (2) that the district court erroneously required plaintiffs to show actual delayed entry or injury to a specific party to establish an antitrust violation; (3) that the district court failed to require defendants to prove that the reverse payment promoted the claimed procompetitive benefits of settlement; and (4) that the district court erred when it found the reverse-payment settlement agreement lawful in part based on a provision that allowed the parties to abandon their agreement if the FTC objected to it.

**In re: Nexium (Esomeprazole) Antitrust Litigation, Brief of Amicus Curiae Federal Trade Commission in Support of No Party**, Nos. 15-2005, 15-2006, 15-2007 (1st Cir. February 12,

2016) ([https://www.ftc.gov/system/files/documents/amicus\\_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf)). The case involves an alleged reverse payment agreement between defendants AstraZeneca Pharmaceuticals, manufacturer of the brand drug Nexium, and Ranbaxy, the "first filer" for a generic version of the blockbuster heartburn drug. The plaintiffs in this private antitrust action are purchasers of Nexium—including health insurers, drug wholesalers, and retail pharmacies that bought the drug directly from the manufacturers. The plaintiffs alleged that AstraZeneca made substantial payments to generic challenger Ranbaxy and, in return, Ranbaxy gave up its patent claim and stayed out of the market for six years. After trial, the jury concluded that AstraZeneca had made a large and unjustified reverse payment to Ranbaxy that had an anticompetitive effect. But it also found that the plaintiffs did not prove that AstraZeneca and Ranbaxy would have agreed to an earlier entry date even without the payment. Interpreting the jury's verdict, the district court held that the plaintiffs had not proved that they actually paid more for Nexium than they otherwise would have, and therefore had not established an antitrust violation.

On appeal to the First Circuit, the Commission filed an *amicus* brief on February 12, 2016. The brief took no position on the merits of the case, but instead explained that the district court missed the important distinction between an antitrust violation and an injury-in-fact. The

Commission explained that, under both the Supreme Court’s decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) and other established antitrust precedent, the existence of an antitrust violation – which requires a showing of harm to the competitive process – is distinct from the question of antitrust standing, which requires the plaintiff to show that it suffered an injury-in-fact caused by the violation. The Commission’s brief argued that the district court’s mistaken analysis threatened to add an unwarranted additional burden to federal antitrust enforcement by effectively requiring the government to take on additional proof requirements that, under the law, are to be borne only by private plaintiffs. This additional requirement is particularly inappropriate in the context of a reverse payment, which, the Supreme Court explained, can harm competition by eliminating the risk of potential competition.

**American Sales Co., et al. v. Warner-Chilcott Co., LLC, et al., Brief of Federal Trade Commission as Amicus Curiae in Support of Plaintiffs-Appellants**, No. 14-2071 and 15-1250 (1<sup>st</sup> Cir. June 16, 2015) ([https://www.ftc.gov/system/files/documents/amicus\\_briefs/american-sales-co.et-al.plaintiffs-appellants-v.warner-chilcott-co.llc-et-al.defendants-appellees/1506warner-chilcottamicusbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/american-sales-co.et-al.plaintiffs-appellants-v.warner-chilcott-co.llc-et-al.defendants-appellees/1506warner-chilcottamicusbrief.pdf)). The case involves patent settlement agreements between defendants Warner Chilcott, manufacturer of the brand drug Loestrin 24, and several generic pharmaceutical companies that sought to challenge Warner Chilcott’s patent on the oral contraceptive drug and sell generic versions. Plaintiffs in this private action alleged that the generics agreed to drop their patent challenges in exchange for Warner Chilcott’s agreement to provide various non-cash forms of compensation. Plaintiffs charged that, among other compensation mechanisms, Warner Chilcott induced Watson to stay out of the market for a defined period by promising that, once Watson (the first generic applicant on Loestrin 24) finally did enter, Warner Chilcott would not compete against Watson with an authorized generic (AG) version of Loestrin 24 for six months (a “no AG commitment”).

The district court dismissed this case because the consideration Warner Chilcott paid its rivals was in kind rather than in cash. In its June 16, 2015, amicus brief, the Commission urged the First Circuit to reverse the district court’s ruling and remand it for further proceedings. The Commission argued that the district court’s narrow reading of *Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), was incorrect and would “enable parties to avoid antitrust scrutiny of anticompetitive reverse-payment settlements simply by avoiding the use of cash.” That limitation, the Commission argued, “would illogically elevate form over economic substance.” The Commission explained that “Actavis did not even suggest, let alone hold, that antitrust scrutiny extends only to cash-based reverse-payments; rather, the Court explained that traditional antitrust analysis applies broadly to ‘patent-related settlement agreements’ and ‘overly restrictive patent licensing agreements.’” 133 S. Ct. at 2231-34.

**In re: Lamictal Direct Purchaser Antitrust Litigation, Federal Trade Commission Brief as Amicus Curiae**, Master File No.: 12-995 (WHW-MCA) (D. N.J. October 5, 2012); **Brief of Federal Trade Commission as Amicus Curiae in Support of Plaintiffs-Appellants**, No. 14-1243 (3d Cir. April 28, 2014). The case involves a patent settlement agreement between defendants GlaxoSmithKline (GSK), manufacturer of the brand drug Lamictal, and Teva Pharmaceutical, the “first-filer” for a generic version of GSK’s Lamictal. Plaintiffs in this private action alleged that Teva agreed to delay introduction of its generic version of GSK’s blockbuster Lamictal. According to the complaint, as part of the settlement agreement signed in 2005, GSK entered into an exclusivity license in which it effectively agreed to refrain from marketing an

authorized generic (AG) version of Lamictal during Teva's first-filer exclusivity (a "no AG commitment"), and Teva agreed not to compete with GSK's brand Lamictal tablet until January 2008.

The defendants argued that GSK's no-AG commitment did not constitute a payment under the Third Circuit's ruling in *In re K-Dur Antitrust Litig.*, No. 10-2077, 2012 WL 2877662 (3d. Cir. July 16, 2012). In its October 5, 2012, *amicus* brief, the Commission argued that a no-AG commitment "provides significant value to a first-filer generic company and has become 'a common form of compensation to generics' to induce delayed entry; it 'should therefore be analyzed in the same manner as other forms of consideration paid to generics.'" ([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-lamictal-direct-purchaser-antitrust-litigation/121005lamictalamicusbrief.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/121005lamictalamicusbrief.pdf)). The court granted defendants' motion to dismiss, limiting its application of the *K-Dur* decision to agreements involving payments of cash, and the plaintiffs appealed.

Before any briefing occurred, the Third Circuit remanded the case to the district court after the Supreme Court held that "reverse payment" patent settlements – agreements in which a brand-name drug manufacturer pays a would-be competitor to abandon its patent challenge and agree not to sell its generic drug product for a number of years – are not immune from antitrust scrutiny. *Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The district court again dismissed the case finding that agreements between branded and generic drug manufacturers that include a branded firm's commitment not to introduce an AG could not violate the antitrust laws under *Actavis* because they do not involve cash payments. Again, the plaintiffs appealed.

On appeal to the Third Circuit, the Commission filed an *amicus* brief on April 28, 2014, urging the court to reverse the district court's dismissal. ([https://www.ftc.gov/system/files/documents/amicus\\_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf)). The Commission argued that the *Actavis* decision reaffirmed that "that patent law confers no broad immunity on parties to ... [patent settlement] agreements" and such agreements not to compete could violate the antitrust laws. The Commission explained that the defendants' "[n]o-AG commitment [had] all the hallmarks of the kind of settlement that the Supreme Court held is subject to antitrust scrutiny," and thus should be treated in the same fashion. The Commission pointed out that the "district court elevated form over substance when it concluded that such reverse payments trigger antitrust scrutiny only when they are made in cash... and [t]hat rationale would perversely allow [settling] parties ... to avoid antitrust review by sharing their enhanced monopoly profits in a form other than cash."

**In re: Effexor XR Antitrust Litigation, Brief of the Federal Trade Commission as Amicus Curiae**, No. 3:11-cv-05479 (D. N.J. August 10, 2012); **Brief of the Federal Trade Commission as Amicus Curiae**, No. 3:11-cv-05479 (D. N.J. August 14, 2013); **Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiffs-Appellants**, No. 3:11-cv-05479 (3d. Cir. November 17, 2015); **Supplemental Brief of Amicus Curiae Federal Trade Commission Supporting Plaintiffs-Appellants**, Lead Case No. 3:11-cv-05479-PGS-LHG (3d. Cir. March 17, 2016). The case involves a patent settlement agreement between defendants Wyeth Pharmaceuticals, manufacturer of the brand drug Effexor XR, and Teva Pharmaceutical, the "first filer" for a generic version of Effexor XR. Plaintiffs in this private antitrust action alleged



that Teva agreed to delay introduction of its generic version of Wyeth's blockbuster antidepressant drug Effexor XR. As part of the settlement agreement signed in 2005, Wyeth allegedly agreed to refrain from marketing an authorized generic (AG) version of Effexor XR during Teva's first-filer exclusivity (a "no-AG commitment"), and Teva agreed not to compete with Wyeth's brand Effexor XR until July 1, 2010.

The defendants argued that Wyeth's no-AG commitment did not constitute a payment under the Third Circuit's ruling in *In re K-Dur Antitrust Litig.*, No. 10-2077, 2012 WL 2877662 (3d. Cir. July 16, 2012). In its August 10, 2012, *amicus* brief, the Commission explained that a no-AG commitment "provides significant value to a first-filer generic company and is now 'a common form of compensation to generics' to induce delayed entry; it 'should therefore be analyzed in the same manner as other forms of consideration paid to generics.'"

([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-effexor-xr-antitrust-litigation/120810effexoramicusbrief.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-effexor-xr-antitrust-litigation/120810effexoramicusbrief.pdf)).

Subsequently, the Supreme Court held that "reverse payment" patent settlements – agreements in which a brand-name drug manufacturer pays a would-be competitor to abandon its patent challenge and agree not to sell its generic drug product for a number of years – are not immune from antitrust scrutiny. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). In supplemental briefs on the motion to dismiss filed after the *Actavis* decision, defendants argued that the antitrust analysis required by the Supreme Court in *Actavis* did not apply to their agreement because the agreement did not involve a cash payment. In response, the Commission filed an *amicus* brief on August 14, 2013, explaining that the allegations raised "the same type of antitrust concern that the Supreme Court identified in *Actavis*," and thus should be treated in the same fashion.

([http://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-effexor-xr-antitrust-litigation/130816effexoramicusbrief.pdf](http://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-effexor-xr-antitrust-litigation/130816effexoramicusbrief.pdf)). The Commission pointed out that "accepting the defendants' claim of immunity whenever patentees use vehicles other than cash to share profits from an agreement to avoid competition elevates form over substance, and it would allow drug companies to easily circumvent the ruling in *Actavis*, at great cost to consumers."

In October 2014, the district court dismissed plaintiffs' reverse-payment claims. In its November 17, 2015, *amicus* brief, the Commission argued that the court mistakenly relied on the parties' advance submission of their settlement agreement to the FTC pursuant to a 2002 consent order "as evidence of a lack of intent to violate the antitrust laws [and]...erroneously regarded the agency's decision not to object at that time as a basis for insulating the settlement agreement from antitrust review." The Commission further argued that courts impute no legal significance to agency inaction because "an agency decision whether to act in a particular matter or at a particular time "often involves a complicated balancing" of factors." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). The Commission explained, "[i]f the district court's ruling to the contrary were correct, resource limitations or other factors affecting agency enforcement discretion could perversely immunize anticompetitive agreements from antitrust scrutiny."

([https://www.ftc.gov/system/files/documents/amicus\\_briefs/brief-amicus-curiae-federal-trade-commission-supporting-plaintiffs-appellants/151117curiaebrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/brief-amicus-curiae-federal-trade-commission-supporting-plaintiffs-appellants/151117curiaebrief.pdf)).

On March 17, 2016, the FTC submitted a supplemental *amicus* brief to the Third Circuit addressing defendants' argument that their settlement agreement is exempt from antitrust scrutiny under the Noerr doctrine. The Commission explained that the Supreme Court has made



clear that the Noerr doctrine protects advocacy, not commercial activity. The Commission stated that litigation settlements among private parties are private commercial agreements, and that entry of a consent decree does not confer Noerr protection.

([https://www.ftc.gov/system/files/documents/amicus\\_briefs/re-effexor-xr-antitrust-litigation/160317effexorbriefs.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/re-effexor-xr-antitrust-litigation/160317effexorbriefs.pdf)).

**In re: K-Dur Antitrust Litigation, Brief of the Federal Trade Commission as *Amicus Curiae* Supporting Appellants and Urging Reversal**, Nos. 10-2077, 10-2078, 10-2079 (3d. Cir. May 18, 2011) ([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-k-dur-antitrust-litigation/110518amicusbrief.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-k-dur-antitrust-litigation/110518amicusbrief.pdf)). This case involves patent settlement agreements between defendants Schering-Plough Corporation, manufacturer of the brand drug K-Dur 20, and Upsher Smith and ESI, “first filers” of generic versions of K-Dur 20. Plaintiffs in this private antitrust action alleged that Upsher Smith and ESI agreed to delay introduction of their versions of Schering’s high blood pressure medication K-Dur 20 in exchange for substantial cash payments and other considerations from Schering.

The district court dismissed the case, holding that the patent settlement agreements did not violate the antitrust laws because they fell within the “scope of Schering’s patent.” In its May 18, 2011, *amicus* brief, the Commission urged the Third Circuit to reverse the district court’s ruling. The Commission argued that the reverse payment should be scrutinized under the antitrust rule of reason. The Commission asked the court to consider the agreements not to compete presumptively illegal and condemn them unless the companies can show that their agreements do not harm competition. The Commission further argued that upholding the lower court’s decision would allow branded companies to pay generic companies to stay out of the market until patent expiration. Finally, the Commission argued that the district court’s decision conflicted not only with basic antitrust principles, but also with patent law and the policies of the Hatch-Waxman Act, which Congress enacted to encourage competition by generic drug firms.

**In re: Ciprofloxacin Hydrochloride Antitrust Litigation (Arkansas Carpenters Health and Welfare Fund v. Bayer AG, Bayer Corp.)**, Brief of Amicus Curiae Federal Trade Commission, In Support of Appellants and Urging Reversal, No. 2008-1097 (Fed. Cir. January 25, 2008); **Brief Amicus Curiae of Federal Trade Commission In Support of Rehearing *En Banc***, Docket No.’s 05-2851-cv (L) and 05-2852-cv (CON 2d. Cir. May 20, 2010). 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 district court granted summary judgment based on the “scope of the patent” test. In a brief to the Federal Circuit, the Commission urged the court to reverse the district court’s decision and

argued that the district court's ruling was not compelled by the patent laws and conflicted with fundamental antitrust principles.

([https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-amicus-curiae-brief-re-ciprofloxacin-hydrochloride-antitrust-litigation-concerning-drug-patent/080129cipro.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-amicus-curiae-brief-re-ciprofloxacin-hydrochloride-antitrust-litigation-concerning-drug-patent/080129cipro.pdf))

Some of the plaintiffs' appeals were heard by the Second Circuit, which also affirmed, holding that its prior ruling in *Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2005), was dispositive. See Docket No.'s 05-2851-cv (L) and 05-2852-cv (CON) (2d Cir. April 29, 2010). 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*. (<https://www.ftc.gov/news-events/press-releases/2010/05/ftc-files-amicus-brief-support-rehearing-ciprofloxacin-pay-delay>).

**In re: Tamoxifen Citrate Antitrust Litigation, Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants' Petition for Panel Rehearing and Rehearing En Banc**, Case No. 03-7641 (2d Cir. November 30, 2005)

([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-tamoxifen-citrate-antitrust-litigation/051202amicustamoxifen.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-tamoxifen-citrate-antitrust-litigation/051202amicustamoxifen.pdf)). The Second Circuit 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 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 panel's 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.

**B. Market Definition**

**Regeneron Pharmaceuticals Inc. v. Novartis Pharma AG, et al., Brief for the United States of America and the Federal Trade Commission as Amici Curiae in Support of Neither Party**, Case No. 22-427 (2d Cir. June 17, 2022) (<https://www.justice.gov/atr/case/regeneron-pharmaceuticals-inc-v-novartis-pharma-ag-et-al>). In this case, a private plaintiff, Regeneron Pharmaceuticals, alleged that the defendant, Novartis, conspired with its manufacturing partner, Vetter Pharma International GmbH, in an attempt to monopolize and restrain trade in the anti-VEGF (vascular endothelial growth factor) market. The prescription medications in this market are used to treat several serious diseases through eye injections. According to the complaint, the products are sold in two forms: vials and prefilled syringes. Either form may be used to deliver the same medication, but the prefilled syringes are easier to use and present a lower risk of infection. Novartis owns a patent on prefilled syringe products. The district court dismissed Regeneron's complaint on the grounds that the relevant market could not be limited to prefilled syringes. The question on appeal is whether the plaintiff plausibly alleged that prefilled syringes constitute an antitrust product market or whether the relevant market must also include the vial dosage forms.

The FTC and the DOJ take no position on the ultimate question on appeal. Instead, the amicus brief explains why the district court erred in its analysis of whether Regeneron adequately pleaded a relevant product market. First, the district court concluded that the relevant product market must include both vials and prefilled syringes because those products are functional substitutes. However, the amicus brief explains that whether products are reasonably interchangeable depends on whether the price of one product sufficiently constrains the price charged for the other product. The district court also concluded that, absent extraordinary circumstances, a relevant product market cannot be limited to the products covered by a patent. The amicus brief explains that this reasoning is flawed and out of step with governing legal principles of antitrust market definition, which apply equally to patented and unpatented products.

**Staley v. Gilead Sciences Inc., Federal Trade Commission’s Brief as *Amicus Curiae***, Case No. 3:19-cv-02573-EMC (N.D. Cal. Oct. 25, 2019) (<https://www.ftc.gov/news-events/press-releases/2019/10/ftc-amicus-brief-explains-relevant-antitrust-markets-should-be>). In this case, the private plaintiffs alleged that Gilead and three other manufacturers of branded HIV medications took various anticompetitive actions that resulted in higher prices for products known as combined antiretroviral therapy drugs. The complaint alleged that at least two antitrust product markets were relevant to assessing anticompetitive effects because the challenged conduct harmed competition in multiple ways. Defendant Gilead asked the court to dismiss the complaint, based in part on an argument that the overlapping markets alleged were “contradictory” and therefore improper as a matter of law. The FTC amicus brief takes no position on the underlying factual assertions or the ultimate disposition of Gilead’s motion to dismiss. The FTC amicus brief explains that Gilead’s argument on market definition is inconsistent with core legal principles governing market definition in antitrust cases. It notes that market definition is merely a tool to help determine whether challenged conduct is likely to have anticompetitive effects. The brief explains that when multiple types of anticompetitive harm are alleged, multiple markets may be relevant. Market definition always requires sufficient factual support, the brief observes, but defining different product markets to assess different theories of harm is neither “contradictory” nor legally deficient.

### C. Product Hopping

**Mylan Pharmaceuticals, Inc., et al., v. Warner Chilcott Public Limited Company, et al., Federal Trade Commission as Amicus**, Civil Action No. 12-3824 (E.D. Pa. November 21, 2012); **Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant**, No. 12-3824-PD (3d. Cir. September 30, 2015). The case involves allegations that Warner Chilcott engaged in a pattern of conduct, known as “product hopping,” by introducing three successive product reformulations of its antibiotic drug Doryx that offered little or no apparent medical benefit to consumers. Plaintiffs in this private litigation also alleged that each product reformulation was designed to, and did, impede meaningful generic competition and preserve Warner Chilcott’s monopoly profits.

Warner Chilcott moved to dismiss the complaints arguing that the introduction of a new product cannot constitute an antitrust violation. The Commission filed an *amicus* brief explaining that minor, non-therapeutic changes to a branded pharmaceutical product that harm generic competition can constitute exclusionary conduct that violates U.S. antitrust laws.

([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.-et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.-et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf)). The Commission stated, “[a]pplying a per se legal standard, as Warner Chilcott effectively advances here, would entitle brand pharmaceutical companies, as a matter of law, to manipulate the FDA regulatory process and undermine state and federal laws that encourage generic competition.” The court denied defendants’ motions to dismiss, but later granted Warner Chilcott summary judgment finding (1) that plaintiffs had failed to offer evidence that Warner Chilcott had monopoly power and (2) that its product hopping scheme was not exclusionary conduct.

On appeal to the Third Circuit, the Commission filed an *amicus* brief on September 30, 2015, urging the court to reverse the district court’s ruling and remand it with instructions on applying the antitrust laws. ([https://www.ftc.gov/system/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf)). Without taking a position on the ultimate resolution of the case, the Commission argued that the district court erred by ignoring the unique characteristics of pharmaceutical markets in its analysis of monopoly power. The Commission explained that “generics are unique sources of competition for brand-name prescription drugs. Without automatic substitution, the disconnect between prescribing physicians and payors often insulates brand-name prescription drugs from effective price competition, and a given drug may be priced at monopoly levels even if other drugs are therapeutically similar.” The Commission also argued, “the very fact of product-hopping can itself be evidence of monopoly power. The manufacturer of a brand-name drug generally undertakes a product hop to preserve high profits that generic versions of the same drug would undercut but that no alternative drug, competing in the same market, has yet disciplined.”

The Commission argued that the district court also erred in its analysis of exclusionary conduct when it “dismiss[ed] automatic substitution as a mere ‘regulatory windfall’ undeserving of antitrust protection.” The Commission explained, “a monopolist may not avoid antitrust liability simply because the efficient distribution mechanism it destroys was created in part by procompetitive government action.”

#### **D. Restricted Distribution/REMS**

To receive approval from the FDA, generic firms are required to conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the brand drug. This testing process requires a limited amount of the brand product. Certain brand drugs are subject to distribution restrictions that can be used to prevent generic firms from obtaining samples of the brand product for testing purposes. In many instances, these restricted distribution programs are implemented as part of FDA-mandated risk management programs known as Risk Evaluation and Mitigation Strategies (REMS). When Congress authorized the FDA to require REMS programs, it directed that the FDA was not to use such programs to block or delay approval of generic drug products.

**Mylan Pharmaceuticals, Inc. v. Celgene Corporation, Federal Trade Commission’s Brief as Amicus Curia**, Case No. 2:14-CV-2094-ES-MAH (D. N.J. June 17, 2014) ([https://www.ftc.gov/system/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf)). This case involves allegations that Celgene prevented Mylan from offering competing generic versions of Celgene’s brand drug

products, Thalomid and Revlimid, by precluding it from obtaining samples of those drugs to perform necessary testing even though the FDA had determined that Mylan's testing protocols for the proposed generics were sufficient. Both drugs are used to treat several forms of cancer, as well as other serious conditions. Mylan in this private antitrust action alleged that Celgene stalled Mylan's efforts to obtain samples of the drugs by imposing voluminous and unnecessary requests for information, requests that were a pretext to allow Celgene to delay providing samples with an intention of foreclosing potential competition. Defendant Celgene sought dismissal of the case. Celgene argued that, as a matter of law, a private firm is ordinarily free to choose with whom to do business and vertical agreements, such as the ones between a manufacturer and its distributors, rarely raise antitrust concerns.

Without taking a position on the factual merits of the case, the Commission's brief explained that Mylan's antitrust claims are not barred as a matter of law. It described how Mylan's allegations in this case fit within established Supreme Court precedent holding that a monopolist's refusal to sell to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act. It also explained that a distribution agreement between a brand drug manufacturer and its distributors may violate Section 1 of the Sherman Act, and that under established law a brand name drug manufacturer's patents do not reach activities undertaken in connection with bioequivalence testing.

**Actelion Pharmaceuticals Ltd. v. Apotex Inc., Federal Trade Commission's Brief as *Amicus Curiae***, Case No. 1:12-cv-05743-NLH-AMD (D. N.J. March 11, 2013)

([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/actelion-pharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf)). This case involves allegations that Actelion Pharmaceuticals Ltd. prevented Actavis, Apotex, and Roxane from offering competing generic versions of Actelion's brand drug products by precluding them from obtaining samples of those drugs to perform necessary testing. Actelion's Tracleer is used to treat pulmonary arterial hypertension and Zavesca is used to treat type 1 Gaucher disease. Plaintiffs in this private antitrust action alleged that Actelion imposed distribution restrictions that prevented them from buying samples of Actelion's Tracleer and Zavesca through customary distribution channels, and that Actelion refused to sell the products directly, thereby precluding them from meeting Food and Drug Administration requirements for developing generic versions of these drugs.

Defendant, Actelion, argued that it was under "no duty or obligation" to sell its products to potential competitors, whether or not those products fell under the FDA's REMS requirements. In its March 11, 2013, *amicus* brief, the Commission explained that the Hatch-Waxman Act, the regulatory framework designed to encourage the introduction of low-cost generics while preserving incentives for innovation, could not function as Congress intended if generics were unable to access samples of brand products. Without taking a position on the factual merits of the case, the Commission explained that the generic firms' claims were not barred as a matter of law. It described how the allegations in this case fit within established Supreme Court precedent holding that a monopolist's refusal to sell to its potential competitors may, under certain circumstances, violate the antitrust laws. The brief also clarified that a distribution agreement between a brand-name drug manufacturer and its distributors may also violate the antitrust laws, even when a patented product is involved.



## E. Patent Issues

**Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals of New York, LLC, Amneal Ireland LTD., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Inc., Federal Trade Commission as Amicus**, Civil Action No. 23-cv-20964 (D.N.J. March 22, 2024); **Brief for Amicus Curiae Federal Trade Commission Supporting Defendants-Appellees**, Civil Action No. 24-1936 (Fed. Cir. September 6, 2024). In this case, Teva brought a patent infringement suit against Amneal after Amneal sought FDA approval to bring a generic version of asthma inhaler ProAir HFA to market. Since Teva listed its patents for the ProAir HFA inhaler in the FDA's publication of "Approved Drug Products with Therapeutic Equivalence Evaluation," commonly known as the "Orange Book," Teva's patent infringement claims triggered a statutory stay that blocked approval of Amneal's competing drug product for up to 30 months. Amneal argued that Teva improperly listed its patents in the Orange Book and therefore should not have been able to stay approval of Amneal's competing generic product. Amneal further claimed that Teva's improper listing of these products harmed competition.

On March 22, 2024, the Commission filed an *amicus* brief explaining that Teva had improperly listed patents in the FDA's Orange Book and urged the court to order those patents removed, which would clear the way for swifter approval of competing generic products. ([https://www.ftc.gov/system/files/ftc\\_gov/pdf/62-AMICUS-CURIAE-BRIEF-FILED.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/62-AMICUS-CURIAE-BRIEF-FILED.pdf)).

On Appeal to the Federal Circuit, the Commission filed an *amicus* brief on September 6, 2024, again urging the delisting of Teva's patents because they were improperly listed in the FDA's Orange Book, which could ultimately harm competition by delaying or deterring the entry of lower-cost generic products. ([https://www.ftc.gov/system/files/ftc\\_gov/pdf/62-AMICUS-CURIAE-BRIEF-FILED.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/62-AMICUS-CURIAE-BRIEF-FILED.pdf)). On December 20, 2024, the U.S. Court of Appeals for the Federal Circuit affirmed the lower court's order against Teva requiring the drugmaker to delist several asthma inhaler patents from the FDA's Orange Book.

**Mylan Pharmaceuticals, et al. v. Sanofi-Aventis, et al., Brief of Federal Trade Commission as Amicus Curiae in Support of No Party**, No. 2:23-cv-00836-MRH (W.D. Pa. Nov. 20, 2023) (<https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-files-amicus-brief-outlining-anticompetitive-harm-caused-improper-orange-book-listings>). In this case, drug manufacturer Mylan Pharmaceuticals Inc. (Mylan) alleges that Sanofi-Aventis U.S. LLC (Sanofi) engaged in anticompetitive conduct to monopolize the market for injectable insulin glargine, a drug used to treat diabetes. Mylan alleges Sanofi monopolized the injectable insulin glargine market in part by abusing the regulatory process associated with the Food and Drug Administration's (FDA) publication of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Specifically, Mylan alleges that Sanofi delayed and blocked Mylan's generic drug called Semglee from competing with Sanofi's branded insulin glargine drug Lantus by improperly listing several drugs in the Orange Book.

The Commission filed an *amicus brief* in the Western District of Pennsylvania to address the anticompetitive harm that stems from improperly listed patents in the FDA's Orange Book, without taking a position on the merits. As detailed in the FTC's brief, when a brand pharmaceutical company lists a patent in the Orange Book, it may lead to a statutory stay that



blocks the introduction of competing drug products for up to 30 months, including lower-cost generic alternatives. When this stay is triggered by a patent that is improperly filed and does not meet the statutory listing criteria, the stay would delay consumer access to a competing product that might reduce prices, improve quality and access, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for consumers in accessing cost-effective medications, the FTC stated in the brief.

**Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC, Federal Trade Commission's Brief as *Amicus Curiae*, Case No. 21-691-GBW (D. Del., Nov. 10, 2022)**  
(<https://www.ftc.gov/news-events/news/press-releases/2022/11/ftc-amicus-brief-challenges-abuse-fda-orange-book-listing-procedures-block-drug-competition>). Plaintiff Jazz

Pharmaceuticals alleges that defendant Avadel CNS Pharmaceuticals infringed a patent involving the implementation of a REMS distribution system for Jazz's narcolepsy treatment Xyrem, resulting in an automatic stay on FDA approval of Avadel's competing product because Jazz listed the patent in the FDA's Orange Book. Avadel moved for an order delisting Jazz's patent from the Orange Book, citing the statutory requirement that listed patents must claim either the drug itself or a method of its use.

The FTC's amicus brief took no position on the scope or claim construction of Jazz's patent. Instead, it argued that, to the extent that Jazz's patent claims only a REMS distribution system, it is improperly listed the Orange Book and should be delisted. The brief highlights the significant harm to consumers from such improper listings. When a brand company sues a competitor for infringement of an Orange Book listed patent, the FDA is automatically prohibited from approving the competitor's drug for up to 30 months. When triggered by an appropriately listed patent, this 30-month stay reflects Congress's intent to balance the interests of brand and generic drug manufacturers by facilitating the resolution of certain types of patent disputes involving pharmaceutical products. But when this stay is triggered by a patent that does not meet the statutory listing criteria, the stay improperly blocks consumer access to a competing product that might reduce prices, improve quality, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for the public.

**In re: DDAVP Direct Purchaser Antitrust Litigation, Brief for the United States and Federal Trade Commission as Amici Curiae Supporting Plaintiffs-Appellants, No. 06-5525 (2d. Cir. May 25, 2007)**

([https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-and-department-justice-amicus-curiae-brief-re-ddavp-direct-purchaser-antitrust-litigation/ddavpcommission-dojbrief.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-amicus-curiae-brief-re-ddavp-direct-purchaser-antitrust-litigation/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.

**Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc., Brief of Amicus Curiae Federal Trade Commission Supporting Appellant and Urging Reversal**, Case No. 04-1186 (Fed. Cir. March 31, 2004); **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. February 11, 2005). 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 explained 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. ([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/teva-pharmaceuticals-usa-inc.v.pfizer-inc./teva\\_v\\_pfizer.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/teva-pharmaceuticals-usa-inc.v.pfizer-inc./teva_v_pfizer.pdf)). The brief argued 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 argued that the court failed to take account of the fact that, unless Teva could obtain a court decision regarding Pfizer's patent, the FDA could not give Teva approval to market its generic drug until 180 days after the first generic applicant (Ivax Pharmaceuticals) entered the market with its version. The brief also explained that the district court's holding would 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 an *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. (<https://www.ftc.gov/sites/default/files/documents/cases/2005/02/050211amicusbrieftevaparm.pdf>).

**SmithKline Beecham Corporation v. Apotex Corporation, Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpham's Cross Motion for Entry of An Amended Order**, Case No. 99-CV-4304 (E.D. Pa. January 28, 2003) ([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/smithkline-beecham-corp.v.apotex-corp./smithklineamicus.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/smithkline-beecham-corp.v.apotex-corp./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 affect 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.

**In re: Buspirone Patent, Antitrust Litigation, Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss**, 185 F. Supp. 2d 363 (SD. NY. 2002) ([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/re-buspirone-antitrust-litigation/buspirone.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf)). The case 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 made misleading statements 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 was 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 petitions intended to influence governmental decision-making; 2) they do not constitute conduct 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 might deprive BMS of *Noerr* immunity.

**American Bioscience, Inc. v. Bristol-Myers Squibb Co., Brief of the Federal Trade Commission as Amicus Curiae**, No. CV-00-08577 WMB (AJWx) (C.D. Cal. September 1, 2000) (<http://www.ftc.gov/enforcement/cases-proceedings/american-bioscience-inc-v-bristol-myers-squibb-company-does-1-through>). 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.

#### **F. Noerr-Pennington Doctrine**

**Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals (USA), Inc., Federal Trade Commission's Brief as Amicus Curiae**, No. 3:18-cv-01994 (D.N.J.) (<https://www.ftc.gov/policy/advocacy/amicus-briefs/2018/06/takeda-pharmaceutical-company-limited-et-al-v-zydus>). Zydus filed an Abbreviated New Drug Application for FDA approval of a generic version of Takeda's ulcer medication Prevacid SoluTab. As permitted by the Hatch-Waxman Act, Takeda filed a patent infringement lawsuit alleging that Zydus's generic version of Prevacid SoluTab infringed four of Takeda's patents. Zydus filed counterclaims alleging that Takeda's infringement suit constitutes anticompetitive sham litigation. Takeda moved to dismiss Zydus's antitrust counterclaims, arguing in part that, because Takeda has a statutory right to file a patent infringement suit under the Hatch-Waxman Act, its suit cannot be a sham. In its *amicus* brief, the Commission urged the court to reject Takeda's suggestion that patent infringement suits brought under the Hatch-Waxman Act are exempt from antitrust scrutiny. The Commission

argued that the language of the Hatch-Waxman Act, case law, and FDA regulations do not exempt Hatch-Waxman suits from antitrust scrutiny as potential shams.

**Amphastar Pharmaceuticals, Inc., et al. v. Momenta Pharmaceuticals, Inc. et al., Brief of the Federal Trade Commission as Amicus Curiae in Support of Neither Party and in Favor of Reversal**, No. 16-2113(1<sup>st</sup> Cir.). In this case involving allegedly deceptive conduct before a standard-setting organization (SSO), the Commission took no position on the ultimate merits of the case, but urged reversal of the district court's misapplication of the *Noerr-Pennington* doctrine. (<https://www.ftc.gov/policy/advocacy/amicus-briefs/2016/11/amphastar-pharmaceuticals-inc-et-al-v-momenta-pharmaceuticals>). Amphastar markets a generic drug called enoxaparin, an anticoagulant. Sandoz markets its own enoxaparin in competition with Amphastar through an exclusive license to the '886 patent held by Momenta. The '886 patent covers a testing method for assessing enoxaparin, known as the '207 method. Amphastar alleges that Sandoz and Momenta deceptively induced the relevant private SSO (the United States Pharmacopeial Convention) into adopting the '207 method by failing to disclose the patent. Immediately after Amphastar received FDA approval for enoxaparin and began using the '207 method to market the product, Momenta and Sandoz sued for patent infringement. The district court initially enjoined Amphastar from marketing generic enoxaparin, but then the Federal Circuit vacated the injunction. Amphastar later sued defendants for violations of Sections 1 and 2 of the Sherman Act and its California analog. The district court dismissed the complaint, holding that the Food and Drug Administration's (FDA) purported adoption of the '207 method provided the defendants protection from antitrust claims due to the *Noerr-Pennington* doctrine. While the Commission took no view on the merits, it explained in its amicus brief how the district court misapplied the *Noerr-Pennington* doctrine.

First, the Commission explained the district court failed to identify petitioning conduct before a governmental body, which is an essential requirement of the *Noerr-Pennington* doctrine. The alleged petitioning occurred before a private SSO, a non-governmental organization. No petitioning took place before the FDA, and even if the district court believed that the defendants indirectly petitioned the FDA through the private SSO, the court should have considered the alleged deceptive conduct before the SSO prior to applying *Noerr* protection. Second, the defendants had also argued that *Noerr* foreclosed Amphastar's claims because Amphastar's injuries flowed directly from the defendants' patent suit, which is *Noerr* protected. The Commission rejected this argument, because a subsequent patent suit cannot confer *Noerr* protection on allegedly anticompetitive conduct before a private SSO. *Noerr* protection does not attach to the unlawful acquisition of market power merely because that market power is subsequently exploited through litigation.

### **G. Regulatory Issues**

**Sage Chemical, Inc. et al. v. Supernus Pharmaceuticals, Inc. et al., Brief for the Federal Trade Commission as Amicus Curiae In Support of Plaintiffs**, No. 1:22-cv-1302-CJB (D. Del. March 23, 2023) (<https://www.ftc.gov/legal-library/browse/amicus-briefs/sage-chemical-inc-et-al-v-supernus-pharmaceuticals-inc-et-al>). Plaintiffs Sage Chemical, Inc. and TruPharma, LLC allege that the defendants engaged in unlawful strategies to delay or block entry of a generic version of Apokyn, a drug used to treat patients with advanced Parkinson's Disease. Many of these strategies leveraged defendants' control over the Apokyn pen injector, an FDA-

required device used to inject either brand or generic apomorphine cartridges, to prevent Parkinson's patients from accessing Plaintiffs' cheaper generic apomorphine cartridges. Defendants filed an omnibus motion to dismiss the complaint in its entirety on January 13, 2023.

The FTC's amicus brief took no position on the liability of the individual or corporate defendants but highlighted four antitrust issues raised by defendants' motion. First, the FTC explained how exclusion of a generic harms not only that competitor, but also competition and consumers. Second, the FTC argued that the Plaintiffs' development of a generic that can be substituted for branded cartridges is not improper "free-riding" under the antitrust laws. Indeed, the governing legal and regulatory framework encourages development of substitutable generic drug products, and the Supreme Court has long made clear that marketing a product designed to work with a different company's product is not improper free-riding. Third, the FTC points out that exclusive agreements can be unlawful when they substantially foreclose a competitor's access to a key input—even if that competitor can theoretically develop its own alternative version of the input. Finally, the FTC argues that defining a relevant antitrust market requires assessing which products are available for consumers to turn to if prices were raised above a competitive level, and there is no deficiency if this analysis results in a relevant market with one product.

**Mylan Pharmaceuticals Inc. v. Sebelius, Federal Trade Commission Corrected Brief as Amicus Curiae**, Civil Action No. 1:12-cv-00524-ESH (D. D.C. April 12, 2012)

([https://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/mylan-pharmaceuticals-inc.v.sebelius/120411mylanamicus.pdf](https://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.sebelius/120411mylanamicus.pdf)). In 2011, Teva Pharmaceuticals USA, Inc. acquired Cephalon, Inc. the exclusive distributor and manufacturer of the brand drug, Provigil. Subsequently, the FDA awarded Teva the 180-day generic exclusivity rights under the Hatch-Waxman Act to market a generic version of Provigil. Mylan Pharmaceuticals, Inc., a generic manufacturer, sued the FDA seeking a preliminary injunction to require the FDA to (1) reverse the generic exclusivity it granted to Teva and (2) approve Mylan's ANDA for a generic Provigil product. Mylan argued that the FDA should disqualify Teva, the branded drug seller, from controlling 180-day generic exclusivity rights because the FDA's decision fundamentally contradicts the purpose of the statutory framework of the Hatch-Waxman Act. The Commission filed a brief as *amicus curiae* and explained that allowing a branded drug company to control the generic exclusivity period would have adverse effects on competition.

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