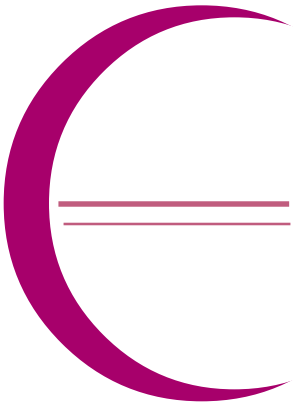

Collusion and Other Anticompetitive Practices:

A Survey of Class Action Lawsuits Against Drug Manufacturers

Collusion and Other Anticompetitive Practices

A Survey of Class Action Lawsuits against Drug Manufacturers

INTRODUCTION

This document summarizes recent and pending class action lawsuits alleging antitrust and consumer fraud violations by pharmaceutical manufacturers. The cases cover three areas of anticompetitive conduct: brand-name drug manufacturer efforts to suppress generic competition and other drug manufacturer collusion to restrict competition; fraud related to drug pricing; and deceptive marketing.

These case summaries are intended to provide a brief sketch of the drug industry's anticompetitive practices that are currently the subject of litigation; this is not an exhaustive list of all litigation related to drug industry anticompetitive practices. These cases summaries also highlight the need for continued industry monitoring, consumer vigilance, and legislative solutions. Upon request, Families USA can provide more detailed information about these cases and the drug industry in general.

Pharmaceutical Class Action Summaries

Collusion and Anticompetitive Practives:
A Survey of Class Action Lawsuits against Drug Manufacturers

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Cases Related to Hatch-Waxman and Other Collusion Cases

LORAZEPAM AND CLORAZEPATE LITIGATION
In re Lorazepam and Clorazepate Antitrust Litigation

BUSPAR LITIGATION
In re Buspirone Antitrust Litigation

CARDIZEM LITIGATION
In re Cardizem CD Antitrust Litigation

CIPRO LITIGATION
In re Ciprofloxacin Hydrochloride Antitrust Litigation

HYTRIN LITIGATION
In re Terazosin Hydrochloride Antitrust Litigation

K-DUR 20 LITIGATION
In re K-Dur 20 Antitrust Litigation

NEURONTIN LITIGATION

NOLVADEX LITIGATION
In re Tamoxifen Citrate Antitrust Litigation

PAXIL LITIGATION

PRILOSEC LITIGATION

PROCARDIA XL LITIGATION

RELAFEN LITIGATION

TAXOL LITIGATION

TIAZAC LITIGATION

Hatch-Waxman Amendments: A Brief Summary

An understanding of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act[1] is necessary in order to appreciate the tactics pharmaceutical companies use to delay and prevent generic competition. A more complete discussion of Hatch-Waxman and the drug approval process is covered in a companion piece, "Overview of Hatch-Waxman: Legislative Background."

Congress enacted Hatch-Waxman in 1984 in part to facilitate the development and expedite the approval of generic drugs. Hatch-Waxman shortened the generic drug approval process by allowing generic manufacturers to file an **Abbreviated New Drug Application** ("ANDA"), incorporating data that the brand-name drug manufacturer has already submitted to the FDA. With the ANDA, the generic manufacturer must make one of four certifications to the FDA regarding each patent the brand-name manufacturer has submitted to the *Orange Book*.[2] The *Orange Book* is a publication that lists all prescription drugs approved for use in the U.S. and the patents covering those drugs. The fourth of these certifications, referred to as a Paragraph IV Certification, is the one that has been manipulated by drug manufacturers to extend brand-name monopolies. With a Paragraph IV Certification, the generic manufacturer claims that the brand drug patent is invalid or will not be infringed by the generic.[3]

When a generic manufacturer files a Paragraph IV Certification, it must notify the patent holder (for simplicity, referred to here as the brand-name drug manufacturer). If the brand-name drug manufacturer sues the generic manufacturer for patent infringement within 45 days of notice, the FDA cannot issue final approval of the generic, or any other generics related to that brand-name drug, for 30 months (the **"30-Month Stay"**) unless the patent expires or there is resolution of the lawsuit. The first generic manufacturer filing an ANDA with a Paragraph IV certification is eligible for 180 days during which its product will be the only generic on the market (the "**Exclusivity Period**"). The Exclusivity Period starts to run either when the generic is commercially marketed or when there is a court decision finding that the patent is either invalid or not infringed by the generic.[4]

Despite the goal of Hatch-Waxman to expand consumer access to generics, the 30-Month Stay and the Exclusivity Period have presented crafty brand-name manufacturers with opportunities to extend their monopolies through a variety of anticompetitive tactics.

30-Month Stay: Since the filing of a patent infringement action within 45 days of notice of a Paragraph IV Certification ANDA delays FDA approval of the generic, brand-name manufacturers have an incentive to claim, obtain, and list as many patents as possible. Even a completely frivolous patent infringement action will preclude FDA approval for up to 30 months. This has resulted in brand-name manufacturers "warehousing" as many patents as they can and filing frivolous lawsuits when notified of a Paragraph IV Certification ANDA.

Exclusivity Period: The Exclusivity Period is important because the first ANDA filer with a Paragraph IV certification—the generic manufacturer entitled to 180 days exclusivity—may control the timing of the product's introduction. As a result, it can determine when the brand-name monopoly ends.[5] FDA final approval does not *require* commercial marketing. The first ANDA filer is permitted to delay marketing as long as it likes, but the FDA cannot grant final approval to any *other* generic until the first ANDA filer gets its 180 days.[6] Creative—but potentially illegal—partnerships between the first ANDA filer and the brand-name drug manufacturer can effectively prevent generic competition for the brand-name drug for an indefinite period. The profits flowing from the brand-name manufacturer's continued monopoly are sometimes shared with the first ANDA filer in exchange for agreeing not to go to market.[7]

Endnotes

[1] The Hatch-Waxman Amendments are more formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355

[2] The Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"). See 21 U.S.C. § 355(j)(7)(A).

[3] 21 U.S.C. § 355(j)(2)(A)(vii).

[4] 21 U.S.C. § 355(j)(5)(B).

[5] See 64 FR 42873, 42874 ("During litigation of many cases related to the 180-day exclusivity, the parties and courts have recognized the potential for the 180-day exclusivity process to substantially delay the entry of competitive generic drug products into the market. This situation can occur when the marketing of any subsequent generic drug product is contingent upon the occurrence of an event that is within the first ANDA applicant 's control.").

[6] David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks , 55 Food & Drug L. J. 321, 332 (2000) ("[T]he first generic firm to challenge a patent holder is the only generic firm that can enter; until it enters, no other generic firm can enter the market.").

[7] Ibid.

LORAZEPAM AND CLORAZEPATE LITIGATION

In re Lorazepam and Clorazepate Antitrust Litigation

Litigation Background

Courts:	United States District Court for the District of Columbia (coordinating several cases filed throughout the country), several state courts
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors), state attorneys general
Defendants:	Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., Cambrex Corporation, Profarmaco S.r.l., Gyma Laboratories of America, Inc., and SST Corporation
Class Period:	January 1, 1998 through December 31, 1999

Market Background

Drug #1:	Brand name: Ativan®, Generic name: lorazepam
Indication:	This medicine is used to relieve anxiety and cause drowsiness before certain medical procedures
Market Size:	$508.2 million (1999)
Drug #2:	Brand name: Tranxene®, Generic name: clorazepate dipostassium
Indication:	This medicine is used to treat nervousness or anxiety, seizures, and alcohol withdrawal
Market Size:	$122.7 million (1999)

Underlying Allegations

The plaintiffs allege that Mylan unlawfully raised prices for its generic clorazepate and lorazepam tablets after entering into profit-sharing and exclusive license agreements with the suppliers and the manufacturers of the drug's active pharmaceutical ingredients (APIs). These agreements deprived other generic manufactures of the APIs necessary to manufacture generic clorazepate and lorazepam tablets. Having gained control of the supply of the necessary APIs, Mylan then raised its prices for clorazepate and lorazepam tablets by staggering amounts (*i.e.*, 1,900 percent to over 6,500 percent) despite no significant increase in Mylan's costs. SST Corporation, the only API distributor that did not have a licensing agreement with Mylan, nonetheless agreed to an implicit price-fixing arrangement with Mylan, indicating that it would be the best partner Mylan ever had regarding lorazepam (*i.e.,* SST would also raise its API prices for lorazepam). Shortly after Mylan's price increases, SST raised the price for lorazepam API significantly. The scheme materially restrained trade and forced consumers taking generic lorazepam and clorazepate tablets to pay substantially higher prices than they would have paid in a freely competitive market.

Status

On February 1, 2002, Chief Judge Thomas F. Hogan approved settlements involving the FTC, state attorneys general, and consumers in the amount of $100 million. The Court also approved class action settlements totaling approximately $35 million for the benefit of third-party payors. *In re Lorazepam & Clorazepate Antitrust Litig.*, __ F.R.D. __, 2002 WL 246664 (D.D.C. Feb. 1, 2002). Pretrial proceedings continue relative to the direct purchaser action, which has been certified for class treatment. *See In re Lorazepam & Clorazepate Antitrust Litig.*, 202 F.R.D. 12 (D.D.C. 2001

BUSPAR LITIGATION

In re Buspirone Antitrust Litigation

Litigation Background

Court:	United States District Court for the Southern District of New York (coordinating several cases filed throughout the country)
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors), state attorneys general
Defendants:	Bristol-Myers Squibb Co.
Class Period:	November 21, 2000 through the present

Market Background

Drug:	Brand name: BuSpar®; Generic name: buspirone
Indication:	This medicine is used to treat anxiety
Market Size:	$591 million (1999)
Brand name manufacturer:	Bristol-Myers Squibb Co.
First filer of ANDA Challenging Patent(s):	Danbury Pharmacal, Inc.
Subsequent ANDA filers:	Mylan Pharmaceuticals, Inc., Par Pharmaceutical, Inc.
Is generic now on the market?	Yes, as of March 2001

Underlying Allegations

Just hours before the patent for buspirone was set to expire at midnight on November 21, 2000, Bristol-Myers improperly submitted a new patent for buspirone to the FDA. Bristol-Myers misrepresented to the FDA that the patent covered a method of using buspirone; the patent actually covered only part of the chemical reaction the drug undergoes once it is ingested. The new patent is not the type of patent that extends a drug manufacturer's right to be the only seller of that drug. Under Hatch-Waxman, however, Bristol-Myers' submission required the FDA to deny applications from other companies that had requested approval to market generic versions of BuSpar®. One company, Mylan Pharmaceuticals, Inc., had generic buspirone loaded on trucks and ready to ship on November 22, 2000. Bristol-Myers' filing, however, precluded FDA approval of Mylan's product and, thus, prevented Mylan from bringing its generic equivalent to market.

In addition, Bristol-Myers settled a patent infringement suit with Danbury Pharmacal, Inc. and its affiliate, Schein Pharmaceuticals, Inc., in 1994. Some of the plaintiffs in that suit allege that Bristol-Myers's settlement was a sham used to cover up an unlawful anticompetitive arrangement under which Schein agreed to stay out of the buspirone market and help maintain a public perception that the patent was valid in return for $72.5 million, even though both parties knew that the patent was not valid.

Status

The class action plaintiffs seek damages under federal and state antitrust law and redress for the defendant's unjust enrichment. On February 14, 2002, the court denied the defendants' motions to dismiss the plaintiffs' claims. In re Buspirone Patent Litig., __ F, Supp. 2d __, 2002 WL 243184, *2 (S.D.N.Y. Feb. 14, 2002).

CARDIZEM LITIGATION

In re Cardizem CD Antitrust Litigation

Litigation Background

Courts:	United States District Court for the Eastern District of Michigan (coordinating several cases filed throughout the country), several state courts
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors), state attorneys general
Defendants:	Hoechst Marion Roussel, Inc., now merged into Aventis Pharmaceuticals, Inc., and Andrx Corporation
Class Period:	July 9, 1998 through June 23, 1999

Market Background

Drug:	Brand name: Cardizem CD®; Generic name: Diltiazem CD
Indication:	This medicine is used to treat high blood pressure and angina (chest pain)
Market Size:	$855 million (1999)
Brand name manufacturer:	Hoechst Marion Roussel, Inc. (HMR)
First filer of ANDA Challenging Patent(s):	Andrx Corporation
Subsequent ANDA filers:	Biovail International Corp., Faulding, Inc.
Is generic now on the market?	Yes, as of June 23, 1999

Underlying Allegations

Under the provisions of Hatch-Waxman, final marketing approval of Andrx's generic version of Cardizem CD® was expected on July 3, 1998. However, on September 24, 1997, HMR and Andrx entered a written agreement whereby (1) Andrx agreed to withhold its product from the market once it received FDA approval, and (2) HMR agreed to pay Andrx $10 million per quarter, pending the resolution of patent infringement litigation between them. On July 9, 1998, the FDA granted final marketing approval to Andrx's product, and HMR began making payments to Andrx. As the first ANDA filer to challenge HMR's patent, Andrx was entitled to 180 days of marketing exclusivity under Hatch-Waxman, during which the FDA would not approve any other generic for marketing. Because Andrx withheld its product, the exclusivity period was not "triggered," and the FDA could not grant marketing approval to Biovail's ANDA. In June 1999, HMR and Andrx ended their agreement and settled the patent litigation. HMR paid Andrx a final sum of $50,700,000, bringing its total payments under the HMR/Andrx Agreement to $89,830,000. Generic competition—which could have begun in July 1998—finally began in June 1999.

Status

The class action plaintiffs seek damages under federal and state antitrust law and redress for the defendant's unjust enrichment. The court granted certain plaintiffs' motions for partial summary judgment, holding that the HMR/Andrx Agreement was *per se* illegal under federal and state antitrust law. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000). An interlocutory appeal of that ruling is pending in the United States Court of Appeals for the Sixth Circuit (No. 002483). Oral argument is scheduled for April 30, 2002 in Cincinnati. In addition, the defendants have entered into consent decrees with the Federal Trade Commission.

CIPRO LITIGATION

In re Ciprofloxacin Hydrochloride Antitrust Litigation

Litigation Background

Courts:	United States District Court for the Eastern District of New York (coordinating several cases filed throughout the country), several state courts
Plaintiffs:	Direct purchasers (drug wholesalers) and indirect purchasers (consumers and third-party payors)
Defendants:	Bayer AG, Bayer Corporation, Barr Laboratories, Inc., Hoechst Marion Roussel, Inc. (HMR, now known as Aventis Pharmaceuticals Inc.), The Rugby Group, Inc., and Watson Pharmaceuticals Inc.
Class Period:	January 8, 1997 through the present

Market Background

Drug:	Brand name: Cipro®; Generic name: ciprofloxacin hydrochloride.
Indication:	This antibiotic is used to treat sinusitis, lower respiratory infections, urinary tract infections, chronic bacterial prostatitis, intra-abdominal infections, bone and joint infections, skin, anthrax, and skin structure infections.
Market Size:	$1 billion (2000)
Brand name manufacturer:	Bayer Corporation
First filer of ANDA Challenging Patent(s):	Barr Laboratories, Inc.
Subsequent ANDA filers:	Mylan Pharmaceuticals, Inc.; Schein Pharmaceutical, Inc.; Novex Pharma; Teva Pharmaceuticals, USA; Geneva Pharmaceuticals, Inc.; Genpharm Inc.; Ranbaxy Pharmaceuticals Inc.; Danbury Pharmacal, Inc.; Novopharm Ltd.
Is generic now on the market?	No

Underlying Allegations

Bayer was engaged in patent infringement litigation against Barr (whose defense was being supported by HMR). On January 8, 1997, the two companies settled the patent infringement litigation and enteredinto an agreement whereby Barr agreed to withdraw its challenge to the Cipro patent in exchange for $49 million paid up front. In addition, the settlement included a "supply agreement," which gave Bayer the option of either (1) supplying product to Barr and HMR for resale as a licensed product, or (2) making quarterly multimillion dollar payments through 2003. Bayer then raised the price for Cipro® in order to fund the payments to Barr and HMR. To date, Bayer has exercised its option to make quarterly payments rather than exercising the distribution option. The agreement essentially allocated the entire United States ciprofloxacin market to Bayer.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. On October 1, 2001, Judge Trager entered an order granting a motion to remand several cases back to state court. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001). The defendants have filed dismissal motions, and the plaintiffs have filed motions for partial summary judgment. These motions are currently being briefed.

HYTRIN LITIGATION

In re Terazosin Hydrochloride Antitrust Litigation

Litigation Background

Court:	United States District Court for the Southern District of Florida (coordinating several cases filed throughout the country)
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors), state attorneys general
Defendants:	Abbott Laboratories, Zenith Goldline Pharmaceuticals, Inc., Geneva Pharmaceuticals, Inc.
Class Period:	March 30, 1998 through the present

Market Background

Drug:	Brand name: Hytrin ®; Generic name: terazosin hydrochloride
Indication:	This medicine is an alpha blocker used to treat high blood pressure and benign pros tatic hyperplasia
Market Size:	$541 million (1999)
Brand name manufacturer:	Abbott Laboratories
First filer of ANDA Challenging Patent(s):	Geneva Pharmaceuticals, Inc.
Subsequent ANDA filers:	Zenith Goldline Pharmaceuticals, Inc.
Is generic now on the market?	Yes

Underlying Allegations

Abbott was engaged in patent litigation and appeals with both Zenith Goldline and Geneva. On March 30, 1998, Abbott received word that the FDA had approved Geneva's generic terazosin hydrochloride capsule. During the following two days, Abbott entered into separate confidential agreements with Zenith Goldline and Geneva Pharmaceuticals to alter each company's rights and responsibilities. Under its March 31, 1998, Settlement Agreement, Zenith Goldline agreed to accept $3 million to join Abbott in dismissing the disputes before the District of New Jersey and the Federal Circuit. It also agreed to accept an additional $6 million per quarter to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, Abbott elected to "allow[ ] Zenith to enter the market," or Abbott's patents expired. On April 1, 1998, Geneva Pharmaceuticals agreed to accept $4.5 million per month from Abbott to refrain from marketing any generic terazosin hydrochloride drug, including its FDA approved capsule, until another drug maker sold a generic version of Hytrin in the United States or Geneva Pharmaceuticals received a final, unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. Geneva Pharmaceuticals and Abbott agreed to continue their court battle over the proposed generic terazosin hydrochloride tablet.

Status

The class action plaintiffs seek damages under federal and state antitrust law and redress for the defendant's unjust enrichment. The court found Abbott's agreements with Zenith Goldline and Geneva Pharmaceuticals to be per se illegal under federal and state antitrust law. *In re Terazosin Hydrochloride Antitrust Litig*., 164 F. Supp. 2d 1340 (S.D. Fla. 2000). In addition, the defendants have entered into consent decrees with the Federal Trade Commission

K-DUR 20 LITIGATION

In re K-Dur 20 Antitrust Litigation

Litigation Background

Court:	United States District Court for the District of New Jersey (coordinating several cases filed throughout the country)
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors), Pennsylvania attorney general
Defendants:	Schering-Plough Corporation, ESI Lederle, Inc., Upsher-Smith Laboratories, Inc., American Home Products Corporation
Class Period:	January 1998 through the present

Market Background

Drug:	Brand name: K-Dur-20; Generic name: potassium chloride
Indication:	This medicine is a potassium supplement used to treat or prevent low potassium levels in the blood
Market Size:	$284 million (1999)
Brand-name manufacturer:	Schering-Plough Corporation.
First filer of ANDA Challenging Patent(s):	Upsher-Smith Laboratories, Inc.
Subsequent ANDA filers:	ESI Lederle, Inc.
Is generic now on the market?	Yes, as of September 2001

Underlying Allegations

When Upsher-Smith and ESI Lederle, Inc. (a division of American Home Products) sought FDA approval to manufacture and distribute a generic form of K-Dur 20®, Schering-Plough sued each company for patent infringement. Schering-Plough then settled both lawsuits with agreements calling for multi-million dollar payments to Upsher-Smith and AHP in exchange for the generic companies' commitment to stay out of the K-Dur 20® market for specified time periods. Because of the exclusivity period available under Hatch-Waxman, these agreements blocked FDA approval of another generic version of K-Dur 20®. These illegal agreements have cost consumers more than $100 million.

Status

On April 2, 2001, the FTC charged Schering-Plough, Upsher-Smith, and American Home Products with entering into anticompetitive agreements aimed at keeping low-cost generic forms of K-Dur 20® off the market. The class action lawsuits are in the initial stages of litigation. The defendants' motions to dismiss are currently being briefed.

NEURONTIN LITIGATION

Litigation Background

Courts:	United States District Courts for the Eastern District of New York and the Southern District of New York
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Pfizer, Inc., Warner-Lambert Company
Class Period:	January 16, 2000 through the present

Market Background

Drug:	Brand name: Neurontin®; Generic name: gabapentin
Indication:	This medicine is an anticonvulsant used to treat seizures associated with epilepsy
Market Size:	$851 million (1999)
Brand name manufacturer:	Pfizer, Inc.
ANDA Challenging Patent(s):	Purepac Pharmaceuticals, Inc. and Apotex Corp.
Is generic now on the market?	No

Underlying Allegations

The patent for the active ingredient in Neurontin®, gabapentin, expired in 1998, and the patent claiming the use of Neurontin® to treat epilepsy expired in 2000. Pfizer and Warner-Lambert have listed other patents with the FDA allegedly related to Neurontin® for the sole purpose of preventing generic competition. The anticompetitive acts of Pfizer and Warner-Lambert involve the filing of sham patent infringement lawsuits against generic competitors seeking to manufacture and market generic formulations of Neurontin when the defendants knew the generic formulations of Neurontin did not infringe any patent they owned. The defendants have also fixed the price of the Neurontin at artificially high levels. Generic pharmaceutical manufacturers, including Purepac Pharmaceuticals, Inc. and Apotex Corp., have filed applications with the FDA requesting approval to market generic versions of Neurontin. In their applications to the FDA, these manufacturers have asserted that their products are bioequivalent to Neurontin® and do not infringe any patent owned by or licensed to Pfizer or Warner-Lambert. The FDA is prevented by Hatch-Waxman from granting final approval of generic formulations of Neurontin® for 30 months from the commencement of patent infringement lawsuits. Due to the conduct of the defendants, no generic formulations for Neurontin® have been approved by the FDA.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The lawsuit is at the initial stages of litigation.

NOLVADEX LITIGATION

In re Tamoxifen Citrate Antitrust Litigation

Litigation Background

Court:	United States District Court for the Eastern District of New York (coordinating several cases filed throughout the country)
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Barr Laboratories, Inc., Zeneca, Inc., Zeneca, Limited, AstraZeneca Pharmaceuticals, L.P., and AstraZeneca PLC.
Class Period:	March 5, 1993 through the present

Market Background

Drug:	Brand name: Nolvadex®, Generic name: tamoxifen citrate
Indication:	This medicine is an anti-estrogen used to treat or prevent breast cancer.
Market Size:	$442 million (2001)
Brand name manufacturer:	Zeneca, Inc., and, following a 1999 merger, AstraZeneca Pharmaceuticals LP
First filer of ANDA Challenging Patent(s):	Barr Laboratories, Inc.
Subsequent ANDA filers:	Pharmachemie, B.V., Mylan Pharmaceuticals, Inc., Novopharm Ltd.
Is generic now on the market?	No

Underlying Allegations

The patent for tamoxifen was found to be unenforceable following a trial. *Imperial Chem. Indus., PLC v. Barr Lab., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992). While an appeal of that judgment was pending, however, private agreements were reached in which Barr agreed to abandon its successful challenge of the tamoxifen patent and to not manufacture and market its own generic tamoxifen in the United States until the expiration of the patent in 2002. In exchange, Zeneca and its former parent, Imperial Chemical Industries, agreed to (1) pay Barr $21 million and (2) supply Barr with Zeneca-manufactured tamoxifen for resale as a "generic" in the United States. As a result of the agreements, Zeneca-manufactured tamoxifen is the only tamoxifenon the market. This agreement has prevented true generic tamoxifen from entering the market and, without competition, there is little price difference between Nolvadex® and the licensed product sold by Barr. If not for this illegal agreement, lower-priced, true generic tamoxifen would have been manufactured by Barr and other generic manufacturers and sold in the United States.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The actions have recently been transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Eastern District of New York. The defendants have filed motions to dismiss, and certain plaintiffs have filed motions to remand their actions back to state court.

PAXIL LITIGATION

Litigation Background

Court:	United States District Court for the Eastern District of Pennsylvania
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	SmithKline Beecham Corporation
Class Period:	January 1, 1998 through the present

Market Background

Drug:	Brand name: Paxil®, Generic name: paroxetine hydrochloride
Indication:	This medicine is a selective serotonin reuptake inhibitor (SSRI) used to treat obsessive-compulsive disorder (OCD), panic disorder, posttraumatic stress disorder (PTSD), and social anxiety disorder. It may also be used to treat depression and other mental illnesses
Market Size:	$1.4 billion (2000)
Brand name manufacturer:	SmithKline Beecham Corporation
First filer of ANDA Challenging Patent(s):	Apotex Corp.
Subsequent ANDA filers:	Zenith Goldline Pharmaceuticals, Inc., Pentech Pharmaceuticals, Inc., Geneva Pharmaceuticals, Inc., Alphapharm PTY, Ltd.
Is generic now on the market?	No

Underlying Allegations

SmithKline stockpiled, time-released, and caused patents to be listed in the *Orange Book* in a manner that has enabled them to extend indefinitely their market monopoly for Paxil®. With every new listed patent, SmithKline has manufactured an opportunity to file patent infringement suits (at least 17 are pending) and automatically delay—for another 30 months—FDA approval of generic paroxetine hydrochloride. SmithKline has brought these objectively baseless lawsuits against generic applicants to invoke the 30-month stay under Hatch-Waxman and block FDA approval for generic entry.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The lawsuit is at the initial stages of litigation. SmithKline's motion to stay the litigation until the conclusion of its patent infringement cases has been denied.

PRILOSEC LITIGATION

Litigation Background

Court:	United States District Court for the Southern District of New York
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Astra Aktiebolag, Aktiebolaget Hassle, AstraZeneca L.P., KBI-E, Inc., KBI, Inc. and Merck & Co., Inc.
Class Period:	April 5, 2001 through the present

Market Background

Drug:	Brand name: Prilosec®; Generic name: omeprazole
Indication:	This medicine is a proton pump inhibitor used to treat ulcers, heartburn, gastroesophageal reflux, and Zollinger-Ellison syndrome
Market Size:	$4.1 billion (1999)
Brand name manufacturer:	AstraZeneca L.P.
First filer of ANDA Challenging Patent(s):	Andrx Pharmaceuticals, Inc.
Subsequent ANDA filer:	Apotex, Inc., Impax Laboratories, Inc., Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., Lek Pharmaceuticals and Chemical Co. D.D., Lek USA, Inc., Eon Labs Manufacturing, Reddy-Cheminor, Inc., Schein Pharmaceuticals, Inc., Kremers Urban Development Co., Schwartz Pharma, Inc., Genpharm, Inc., Zenith Goldline Pharmaceuticals, n/k/a IVAX Pharmaceuticals, Inc.
Is generic now on the market?	No

Underlying Allegations

The patent for the compound omeprazole expired on October 5, 2001. Nonetheless, the defendants have stockpiled, time-released, and caused at least six additional patents to be listed in the *Orange Book* in a manner that has enabled them to extend indefinitely their market monopoly for Prilosec®. With every new patent listed, defendants have manufactured an opportunity to file patent infringement suits (at least 11 are pending) and automatically delay—for another 30 months—FDA approval of generic omeprazole.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The lawsuit is in the initial stages of litigation.

PROCARDIA XL LITIGATION

Litigation Background

Court:	United States District Court for the Northern District of West Virginia
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Pfizer Inc., Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc.
Class Period:	February 28, 2000 through the present

Market Background

Drug:	Brand name: Procardia XL®; Generic name: extended-release nifedipine
Indication:	This medicine is a calcium channel blocker used to treat high blood pressure. Some brands are also used to control angina (chest pain)
Market Size:	$521 million (1999)
Brand name manufacturer:	Pfizer, Inc.
First filer of ANDA Challenging Patent(s):	Mylan Pharmaceuticals, Inc.
Subsequent ANDA filers:	Biovail Corp. International
Is generic now on the market?	Yes, as of February 2001

Underlying Allegations

Mylan, as the first filer of an ANDA that challenged Pfizer's patent, was potentially eligible for a 180-day exclusivity period during which the FDA would not grant final approval to any other generic manufacturer's product. Despite the pendency of patent litigation, Mylan received FDA approval to market a generic version of Procardia XL® 30-mg on December 17, 1999. However, Mylan has never marketed its product. Instead, Mylan entered into an agreement with Pfizer that resulted in the voluntary dismissal of patent litigation and a lucrative distribution arrangement for Mylan to market Pfizer-produced extended-release nifedipine tablets. Mylan attempted to "sit" on its exclusivity period in order to preclude FDA approval of Biovail's ANDA. The FDA rejected that effort in February 2001, holding that Mylan was no longer entitled to an exclusivity period. The FDA approved Biovail's ANDA at that time.

Status

The Court denied Mylan's request for a preliminary injunction against the FDA to vacate the approval of Biovail's ANDA. The defendants' dismissal motions have been briefed and are under consideration. A motion to consolidate the five class actions is also pending.

RELAFEN LITIGATION

Litigation Background

Courts:	United States District Courts for the District of Massachusetts and the Eastern District of Pennsylvania
Plaintiffs:	Direct purchasers (drug wholesalers), indirect purchasers (consumers and third-party payors)
Defendants:	GlaxoSmithKline p.l.c., SmithKline Beecham Corporation, Beecham Group, p.l.c.
Class Period:	1992 through the present

Market Background

Drug:	Brand name: Relafen®; Generic name: nabumetome
Indication:	This medicine is a nonsteroidal anti-inflammatory drug used to relieve the symptoms of arthritis
Market Size:	$446 million (1999.
Brand name manufacturer:	SmithKline Beecham Corporation, GlaxoSmithKline p.l.c.
First filer of ANDA Challenging Patent(s):	Copley Pharmaceutical, Inc. (750 mg), Teva Pharmaceuticals USA (500 mg)
Subsequent ANDA filers:	Eon Labs Manufacturing, Inc.
Is generic now on the market?	No

Underlying Allegations

Since February 1992, SmithKline has marketed prescription nabumetome tablets under the brand name Relafen®. Relafen® has not faced generic competition because SmithKline has continuously relied upon a patent issued for the chemical compound nabumetone to obstruct, delay, and prevent FDA approval of ANDAs submitted by pharmaceutical manufacturers seeking to market generic nabumetome tablets. Although the patent is unenforceable because it was obtained through a pattern of misrepresentation in dealing with the Patent and Trademark Office, SmithKline has nonetheless continuously listed the patent with the FDA. SmithKline then brought baseless patent infringement suits against generic pharmaceutical manufacturers in order to invoke a statutory 30-month stay of the FDA's ability to grant final marketing approval. On August 14, 2001, a judgment was entered in the United States District Court for the District of Massachusetts holding that the patent was invalid and unenforceable because SmithKline Beecham made misrepresentations when dealing with the Patent Office. *In re: '639 Patent Litigation*, 154 F. Supp. 2d 157 (D. Mass. 2001). If not for the defendants' unlawful monopolistic conduct, generic nabumetome tablets would have been on the market no later than August 8, 1998, when the FDA granted tentative approval to a generic manufacturer's ANDA.

Status

Several action lawsuits have been filed recently, but they are not yet coordinated in a single forum. The defendants have filed dismissal motions in some of the actions.

TAXOL LITIGATION

Litigation Background

Courts:	United States District Court for the District of Columbia; Tennessee State Court
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Bristol-Myers Squibb Co.
Class Period:	March 1, 1999 through the present

Market Background

Drug:	Brand name: Taxol®; Generic name: paclitaxel
Indication:	This medicine is used to treat various forms of cancer
Market Size:	$814 million (1999)
Brand name manufacturer:	Bristol-Myers Squibb Co.
First filer of ANDA Challenging Patent(s):	IVAX Pharmaceuticals, Inc.
Subsequent ANDA filers:	Mylan Pharmaceuticals, Inc., Baker Norton, Bedford Laboratories
Is generic now on the market?	Yes

Underlying Allegations

Taxol® was developed by the National Cancer Institute at taxpayer expense and given to Bristol-Myers to market exclusively, without limitations as to price, for what Bristol-Myers promised to be no more than five years. On December 29, 1992, the FDA approved Bristol-Myers' NDA and awarded Bristol-Myers the right to market Taxol® on an exclusive basis for five years (*i.e.*, until December 29, 1997). Bristol-Myers then engaged in a scheme to maintain a monopoly on the drug. In baseless patent infringement suits it filed against a potential competitor, Bristol-Myers' patents were found to be invalid. In August 2000, Bristol-Myers agreed to settle a sham patent lawsuit brought "against" Bristol-Myers by American Bioscience, Inc. (ABI), resulting in the listing of another patent in the *Orange Book*. By virtue of its fraud on the Patent and Trademark Office and the "settlement" of the ABI lawsuit, Bristol-Myers was able to preserve its Taxol® monopoly for an additional 19 months.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The lawsuits are in the initial stages of litigation.

TIAZAC LITIGATION

Litigation Background

Courts:	United States District Courts for the District of Columbia and New Jersey, Arizona state court
Plaintiffs:	Indirect purchasers (consumers and third-party payors)
Defendants:	Biovail Corporation
Class Period:	April 22, 2000 through the present

Market Background

Drug:	Brand name: Tiazac®; Generic name: diltiazem hydrochloride
Indication:	This medicine is a calcium channel blocker used to treat angina (chest pain) and high blood pressure
Market Size:	$196 million (1999)
Brand name manufacturer:	Biovail Corpation
First filer of ANDA Challenging Patent(s):	Andrx Pharmaceuticals, Inc.
Is generic now on the market?	No

Underlying Allegations

Biovail pursued patent litigation against Andrx that resulted in a 30-month stay of FDA approval under Hatch-Waxman. Biovail lost both at trial and on appeal. (See *Biovail Corp. Int. v. Andrx Pharmaceutical, Inc*., 158 F. Supp. 2d 1318 (S.D. Fla. 2000). Biovail subsequently obtained exclusive rights to another patent owned by an independent company. Biovail attempted to change its method of manufacturing Tiazac in order to produce a new and different form of Tiazac® that was no different in terms of safety or efficacy, but which fell within the scope of the new patent. Biovail then caused the FDA to list the newly acquired patent in the *Orange Book* and claimed that the new listing triggered another 30-month stay of the FDA's authority to approve Andrx's generic version

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The lawsuit is in the initial stages of litigation.

Cases Related to Fraud Involving Pricing

LUPRON DEPOT LITIGATION

LUPRON DEPOT LITIGATION

Litigation Background

Courts:	United States District Court for the District of Massachusetts (coordinating several cases filed throughout the country), several state courts
Plaintiffs:	Consumers
Defendants:	TAP Pharmaceutical Products, Inc., Abbott Laboratories, Takeda Chemical Industries, Ltd.
Class Period:	1991 through the present

Market Background

Drug:	Brand name: Lupron Depot; Generic name: leuprolide
Indication:	This medicine is a gonadotropin-releasing hormone (GnRH) agonist used to treat en dometriosis. It may also be used to treat prostate cancer and other conditions as determined by a physician
Theraputic equivalent:	Zoladex®
Market Size:	$748 million (1999)
Brand name manufacturer:	TAP Pharmaceutical, a wholly owned joint venture of Abbott and Takeda

Underlying Allegations

The plaintiffs allege that Abbott, Takeda, and TAP created and implemented a fraudulent marketing and sales scheme to substantially increase the sale of Lupron® and reap unlawful profits at the expense of Medicare patients.

A drug's average wholesale price (AWP) is the price upon which the Medicare reimbursement and copayment rate is based.* Manufacturers set a drug's AWP, and, in nearly all cases, it is considerably higher than the prices private insurers pay. In this case, the Medicare program and Medicare patients paid artificially inflated rates for Lupron®. In the case of Lupron, TAP was selling the drug to physicians at a rate considerably lower than the AWP and instructing physicians to bill based on the AWP, allowing the physicians to profit from the difference.

The plaintiffs also allege that the defendants provided physicians and medical care providers with free samples of Lupron® while instructing those providers to bill the Medicare program and Medicare patients for the free samples. These schemes enabled the defendants to control how much reimbursement physicians made under Medicare for Lupron®. Twenty percent of the inflated Medicare payments come directly from copayments and deductibles paid by Medicare beneficiaries. The spread between the actual cost and the AWP was used to induce physicians to prescribe Lupron® instead of the competitor product, Zoladex®, which had a lower AWP and would have been less costly to Medicare and patients.

Status

A lawsuit by the federal government against TAP settled with TAP paying $875 million, the largest fraud settlement in history. The litigation on behalf of consumers, including Medicare beneficiaries who had to pay 20 percent the cost, is in its initial stages.

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* Medicare Part B pays for physician-administered drugs, which Lupron is, based on 95 percent of AWP; patients have 20 percent coinsurance.

Cases Related to Deceptive Marketing

CLARITIN LITIGATION

COUMADIN LITIGATION
In re Warfarin Sodium Antitrust Litigation

PREMARIN LITIGATION
In re premarin Antitrust Litigation

SYNTHROID LITIGATION
In re Synthroid Marketing Litigation

CLARITIN LITIGATION

Litigation Background

Court:	State Superior Court in New Jersey
Plaintiffs:	Consumers
Defendants:.	Schering-Plough Corp.

Market Background

Drug:	Brand name: Claritin®; Generic name: loratadine
Indication:	This antihistamine is used to treat the symptoms of hay fever and other allergy symptoms, such as watery eyes, runny nose, itching eyes, and sneezing. It may also be used to treat hives
Market Size:	$2.2 billion (1999)
Brand name manufacturer:	Schering-Plough Corp.
Is generic now on the market?	No

Underlying Allegations

The plaintiffs allege that Schering-Plough has engaged in a campaign of misrepresentation that has artificially increased the demand and price for a drug that Schering-Plough's own studies have shown to be effective for only 50 percent of its users. Through its direct consumer advertising, including print media, Web site content, and television advertisements, the plaintiffs specifically allege that Schering-Plough and its advertisers have committed the following acts of consumer fraud: (1) holding Claritin® products out as effective for all users when they are not; (2) failing to disclose the limited efficacy of Claritin® products in Claritin® advertising; and (3) holding Claritin® products out as effective for symptoms associated with seasonal allergies when these symptoms may result from many non-allergic causes not addressed by Claritin®.

Status

Plaintiffs allege that the tremendous scale of Claritin® advertising has enabled Schering-Plough to manipulate the true market for Claritin products by unlawfully increasing its consumer demand, thereby unlawfully increasing the price paid for Claritin®. The lawsuit is in the initial stages of litigation.

COUMADIN LITIGATION

In re Warfarin Sodium Antitrust Litigation

Litigation Background

Courts:	United States District Court for the District of Delaware (coordinating several cases filed through out the country), several state courts
Plaintiffs:	Consumers and third-party payors
Defendant:	DuPont Pharmaceuticals Company
Class Period:	March 1, 1997 through August 1, 2001

Market Background

Drug:	Brand name: Coumadin, Generic name: warfarin sodium.
Indication:	This medicine is an anticoagulant used to prevent blood clots from moving or forming.
Market size:	$462 million (1999)
Brand name manufacturer:	DuPont Pharmaceuticals Company
Generic Manufacturer:	Barr Laboratories, Inc.
Is generic now on the market?	Yes

Underlying Allegations

The plaintiffs allege that DuPont Pharmaceuticals Company disseminated false and misleading information to state formulary boards, the medical community, and others, claiming that there is a lack of bioequivalence or therapeutic equivalence between Coumadin and other warfarin sodium products. The FDA sent letters to DuPont on several occasions demanding that they stop this practice and reiterating that the FDA had found that the generic version was bioequivalent to Coumadin. The plaintiffs allege that DuPont's conduct adversely affected the ability of consumers and third-party payors to make well-informed choices among warfarin sodium products and caused them to purchase Coumadin rather than lower-priced, generic, bioequivalent warfarin sodium.

Status

On August 1, 2001, the court granted preliminary approval of a $44.5 million settlement. The final approval hearing was held on January 23, 2002, and the parties await the court's decision. Claim forms to participate in the settlement are due by April 30, 2002. Additional information may be obtained at (www.coumadinsettlement.com).

PREMARIN LITIGATION

In re premarin Antitrust Litigation

Litigation Background

Court:	United States District Court for the Southern District of Ohio
Plaintiffs:	Direct purchaser (drug wholesalers), indirect purchasers (consumers and third-party payors)
Defendants:	Wyeth-Ayerst Laboratories, Inc., American Home Products Corporation
Class Period:	March 24, 1999 through the present

Market Background

Drugs:	Brand name: Premarin®; Generic name: conjugated estrogens. Therapeutic equivalent brand name: Cenestin®
Indication:	This medicine is an estrogen hormone used to supplement estrogen levels when the body no longer produces enough. It is also used to help prevent osteoporosis (weakened bones). It may also be used to treat cancer
Market Size:	$1 billion (1999)
Brand name manufacturer:	Wyeth-Ayerst Laboratories, Inc.
Therapeutic equivalent manufacturer:	Duramed Pharmaceuticals, Inc.

Underlying Allegations

Although patent protection for Premarin® expired long ago, Premarin continues to command a 99 percent share of the conjugated estrogens market in the United States, with annual sales well over $800 million. The plaintiffs allege that this monopoly is the result of the defendants' ongoing anti-competitive and exclusionary conduct that has blocked consumer access to Cenestin®, a less expensive alternative to Premarin® manufactured by Duramed. The plaintiffs allege that the defendants accomplished this by, among other things, issuing misinformation about Cenestin® designed to discourage consumers from purchasing it. The defendants also used exclusive and "disguised" exclusive contracts with health plans and pharmacy benefits managers that precluded or discouraged these entities from placing Cenestin® on their drug formularies, thereby depriving consumers of access to Cenestin®. During this period, the defendants continued increasing the price of Premarin®.

Status

The class action plaintiffs seek damages and injunctive relief under federal and state antitrust law and redress for the defendant's unjust enrichment. The defendants' dismissal motion and plaintiffs' motions for class certification are currently being briefed.

SYNTHROID LITIGATION

In re Synthroid Marketing Litigation

Litigation Background

Courts:	United States District Court for the Northern District of Illinois (coordinating several cases filed throughout the country), several state courts
Plaintiffs:	Consumers and third-party payors
Defendants:	Knoll Pharmaceutical Company, later purchased by BASF
Class Period:	January 1, 1990 through October 21, 1999

Market Background

Drug:	Brand name:Synthroid®; Generic name: levothyroxine sodium
Indication:	Used to treat hypothyroidism and hyperthyroidism, and as total thyroid replacement therapy
Market Size:	$477 million (1999)
Brand name manufacturer:	Knoll, and later BASF
Is generic now on the market?	Yes

Underlying Allegations

The plaintiffs allege that Knoll wrongfully delayed the publication of a study it commissioned that concluded that less expensive branded and generic versions of levothyroxine sodium were bioequivalent and thus could be substituted for Synthroid®. Despite possession of the study, Knoll continued to advertise and represent to state and federal regulators, consumers, pharmacists, and the medical community that there was "no substitute for Synthroid" and that it was a "superior" product to any other levothyroxine sodium preparation.

Status

In connection with the settlement of this litigation, the defendant paid $107 million to consumers and $45.5 million to third-party payors. Final approval of the settlement was upheld by the Seventh Circuit. *In re Synthroid Marketing Litig.,* 264 F.3d 712 (7th Cir. 2001). Outside of the lawsuit, but in connection with the litigation, defendants will pay over $45 million to state attorneys general and $27.5 million in *cy pres* remedies to the pharmacy industry.

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