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Collusion and Other Anticompetitive Practices:

A Survey of Class Action Lawsuits
Against Drug Manufacturers

Second Edition

January 2003



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INTRODUCTION

On April 15, 2002, Families USA and Blue Cross/Blue Shield hosted a forum titled *Making the Drug Industry Play Fair*, which focused on patent abuse and other anticompetitive practices of the drug industry. In connection with this Forum, Families USA issued its publication *Collusion and Anticompetitive Practices: A Survey of Class Action Lawsuits Against Drug Manufacturers* (Families USA Publication No. 02-101). That document summarized recent and pending class action lawsuits alleging antitrust and consumer fraud violations by pharmaceutical manufacturers. This Second Edition supplements and updates those summaries. The cases described in this report 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 case 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 about the drug industry in general.

In addition, the Federal Trade Commission (FTC) issued a report in July 2002 titled *Generic Entry Prior to Patent Expiration: An FTC Study*, which examined a wide range of tactics and potentially unlawful agreements between pharmaceutical manufacturers. The report is available online at (<http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm>).

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HATCH-WAXMAN AMENDMENTS: A BRIEF SUMMARY

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Hatch-Waxman Amendments: A Brief Summary

An understanding of the Hatch Waxman Amendments to the Federal Food, Drug, and Cosmetic Act¹ 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” (issued by Families USA in April 2002.).

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 that 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 time its product will be the only generic on the market (the Exclusivity Period). The Exclusivity Period starts running 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

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:** Used to relieve anxiety and to cause drowsiness before certain medical procedures
- Market Size:** \$508.2 million (1999)
- Drug #2:** Brand name: Tranxene®, Generic name: ciorazepate dipotassium
- 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 manufacturers 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 APIs 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.*, 205 F.R.D. 369 (D.D.C. 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), *review denied*, 289 F.3d 98 (D.C. Cir. 2002).





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

Defendant: Bristol Myers Squibb Co.

Class Period: November 21, 2000 through March 27, 2001

Market Background

Drug: Brand name: BuSpar®; Generic name: buspirone

Indication: 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' 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.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002). On August 19, 2002, the court granted the direct purchasers' motion for class certification. *In re Buspirone Patent Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002). The indirect purchasers' motion for class certification is still pending. Earlier this month, it was announced that Bristol-Myers reached settlements totaling \$410 million with the private plaintiffs and state attorneys general.



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:** 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 defendants' 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. 00-2483). In addition, the court certified a class of direct purchasers, *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297 (E.D. Mich. Mar. 14, 2001), *leave to appeal denied*, No. 01-0107 (6th Cir. June 18, 2001), and an exemplar class of indirect purchasers, *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001) (addressing Michigan class only), *leave to appeal denied*, No. 01-0109 (6th Cir. June 18, 2001). On November 26, 2002, Judge Nancy G. Edmunds granted final approval to a class action settlement with the direct purchasers in the amount of \$110 million. Several actions remain pending.





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:** 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 entered into 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 defendants’ unjust enrichment. On October 1, 2001, the court 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. The court has not yet ruled on these motions, which were argued on December 11, 2002.



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 (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 August 13, 1999

Market Background

Drug: Brand name: Hytrin®; Generic name: terazosin hydrochloride

Indication: Used to treat high blood pressure and benign prostatic 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 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. In April 1998, Geneva Pharmaceuticals agreed to accept \$4.5 million per month from Abbott to refrain from marketing generic terazosin hydrochloride, 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 plaintiffs seek damages under federal and state antitrust law and redress for the defendants' 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). An interlocutory appeal of that ruling is pending in the United States Court of Appeals for the Eleventh Circuit (No. 02-90011-J). The court has granted, in part, and denied, in part, motions to dismiss indirect purchaser claims. *See In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365 (S.D. Fla. 2001). On September 20, 2001, the court granted a motion to certify a class of direct purchasers. *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D 551 (S.D. Fla. 2001).





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:** 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. A trial was held before an FTC administrative law judge who, in a June 27, 2002 ruling, rejected the FTC enforcement division's case. *In the Matter of Schering Plough Corp.*, No. 9297, 2002 WL 1488085 (FTC June 27, 2002). An appeal is now pending before the full Commission. The class action lawsuits are in the initial stages of litigation. The defendants' motions to dismiss have been argued and the parties await ruling.



IN RE NEURONTIN ANTITRUST LITIGATION

Litigation Background

- Courts:** 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)
- Defendants:** Pfizer, Inc., Warner Lambert Company
- Class Period:** January 16, 2000 to the present

Market Background

- Drug:** Brand name: Neurontin®; Generic name: gabapentin
- Indication:** 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 that they owned. The defendants have also fixed the price of 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 defendants' unjust enrichment. The actions have recently been transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the District of New Jersey.





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 to the present

Market Background

Drug: Brand name: Nolvadex®, Generic name: tamoxifen citrate

Indication: 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 tamoxifen on 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 supplied product distributed by Barr. If not for this illegal agreement, lower priced, truly 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 defendants’ unjust enrichment. On August 26, 2002, the court denied plaintiffs’ motion to remand certain cases back to state court. *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326 (E.D.N.Y. 2002). The defendants’ motions to dismiss have been argued, and the parties await ruling.



PAXIL LITIGATION

Litigation Background

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

Market Background

Drug: Brand name: Paxil®, Generic name: paroxetine hydrochloride
Indication: 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 Beecham stockpiled, time released, and caused patents to be listed in the Orange Book in a manner that has enabled them to indefinitely extend their market monopoly of Paxil®. With every new patent listed, SmithKline has manufactured an opportunity to file patent infringement suits (at least 17 were filed) 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 motions to dismiss and stay the litigation have 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 to the present

Market Background

Market Drug: Brand name: Prilosec®; Generic name: omeprazole

Indication: 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 filers: Apotex, Inc., Impax Laboratories, Inc., Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., Lek Pharmaceuticals and Chemical Co, D.D., Lek USA, Inc., EonLabs 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, but imminent

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 of 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 sought damages and injunctive relief under federal and state antitrust law and redress for the defendants' unjust enrichment. On June 21, 2002, the court granted defendants' motion to dismiss the case. *Twin City Bakery Workers and Welfare Fund v. Astra Aktiebolag*, 207 F. Supp.2d 221 (S.D.N.Y. 2002).



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 to the present
Market Background	Drug:	Brand name: Procardia XL®; Generic name: extended release nifedipine
	Indication:	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 pending 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. <i>Mylan Pharmaceuticals, Inc. v. Thompson</i> , 207 F. Supp.2d 476 (N.D.W.Va. 2001). The court has granted defendants' motions to dismiss two class actions and granted, in part, and denied, in part, motions to dismiss three class actions. The three surviving class actions have been consolidated for purposes of discovery.





RELAFEN LITIGATION

In re Relafen Antitrust Litigation

Litigation Background	Courts:	United States District Courts for the District of Massachusetts
	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 to the present
Market Background	Drug:	Brand name: Relafen®; Generic name: nabumetome
	Indication:	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?	Yes
Underlying Allegations	<p>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 statutory 30 month stays 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. <i>In re: '639 Patent Litigation</i>, 154 F. Supp. 2d 157 (D. Mass. 2001), <i>aff'd sub. nom SmithKline Beecham Corp. v. Copley Pharmaceutical, Inc.</i>, 45 Fed. Appx. 915 (Fed. Cir. Aug 15, 2002), <i>rehearing and rehearing en banc denied</i> (Fed. Cir. Oct 16, 2002). 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.</p>	
Status	Several class action lawsuits have been coordinated in the United States District Court for the District of Massachusetts. A trial has been scheduled for January 2004.	



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); state attorneys general
Defendant: Bristol Myers Squibb Co.
Class Period: March 1, 1999 to the present

Market Background

Drug: Brand name: Taxol®; Generic name: paclitaxel
Indication: 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. Early in January 2003, it was announced that Bristol-Myers reached settlements totaling \$135 million with the private plaintiffs and state attorneys general.





TIAZAC LITIGATION

Litigation Background

Courts: United States District Court for the District of Columbia
Plaintiffs: Indirect purchasers (consumers and third party payors)
Defendant: Biovail Corporation
Class Period: March 6, 2000 to the present

Market Background

Drug: Brand name: Tiazac®; Generic name: diltiazem hydrochloride
Indication: A calcium channel blocker used to treat angina (chest pain) and high blood pressure
Market Size: \$196 million (1999)
Brand name manufacturer: Biovail Corporation
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. Biovail has answered the complaint, and the parties are proceeding with discovery.



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 to the present

Market Background

Drug: Brand name: Lupron Depot®; Generic name: leuprolide

Indication: A gonadotropin releasing hormone (GnRH) agonist used to treat endometriosis that may also be used to treat prostate cancer and other conditions as determined by a physician

Therapeutic 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 increase the sale of Lupron® and reap unlawful profits at the expense of Medicare patients. For Medicare covered drugs, reimbursement and co-payments are based on a drug's average wholesale price (AWP).^{*} Manufacturers set the 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. TAP was selling the drug to physicians at a rate much lower than the AWP and instructing physicians to bill based on the AWP, thus allowing the physicians to profit from the difference.

Additionally, the plaintiffs 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 was settled with TAP paying \$875 million, the largest fraud settlement in history. The class action on behalf of consumers, including Medicare beneficiaries who had to pay 20 percent the cost, is proceeding with discovery.

^{*} 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
Defendant: Schering Plough Corp.

Market Background

Drug: Brand name: Claritin®; Generic name: loratadine
Indication: An 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 was dismissed by the trial court and an appeal is pending.





COUMADIN LITIGATION

In re Warfarin Sodium Antitrust Litigation

Litigation Background	Courts:	United States District Court for the District of Delaware (coordinating several cases filed throughout 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:	An anticoagulant used to prevent blood clots from forming or moving
	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 30, 2002, the Court granted final approval to a \$44.5 million settlement. <i>See In re Warfarin Sodium Antitrust Litig.</i> , __ F. Supp. 2d __, 2002 2 Trade Cas. ¶73,791, 2002 WL 2007850 (D. Del. Aug. 30, 2002). An appeal is pending.	



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 to 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) and 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 defendants' unjust enrichment. Defendants' dismissal motion and plaintiffs' motions for class certification are currently pending.





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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