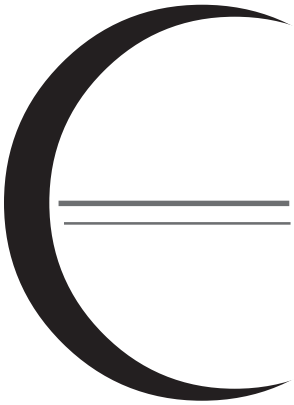

BIG PHARMA BEHAVING BADLY

A Survey of Selected Class Action Lawsuits Against Drug Companies

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Wrongly convicted of murdering his wife, Dr. Richard Kimball escaped from prison and set out on the mean streets of Chicago to find the real killer and prove his innocence. All the while, he was relentlessly pursued by a wisecracking U.S. Marshal, Deputy Samuel Girard, who would stop at nothing until Kimball was behind bars. Gerard and Kimball doggedly followed the trail of clues until the truth finally emerged. Pharmaceutical giant Devlin-McGregor ("nine billion dollars in sales last year alone") had dispatched a one-armed hit man to knock off Dr. Kimball because he had stumbled across evidence that Provasic—Devlin-McGregor's new blockbuster drug—caused liver damage, a serious side effect. Devlin-McGregor sought to suppress this inconvenient fact in order to protect the lucrative Provasic market. In the end, Dr. Kimball was vindicated, and all evildoers were brought to swift justice.

The story line of the 1993 film *The Fugitive*, starring Harrison Ford and Tommy Lee Jones, was pure fiction. Of course, pharmaceutical companies wouldn't really risk the health of patients just to make truckloads of money—would they?

Well, at least they wouldn't hire hit men. While perhaps not fodder for Hollywood screenwriters, the recent past has shown that pharmaceutical companies will go to great lengths to generate cash flow, as illustrated by the following examples in this profile of some of the recent litigation involving drug companies.

Selected Cases Involving Drug Marketing and Pricing

Neurontin® (Parke-Davis, subsequently acquired by Pfizer)

Neurontin® was approved by the FDA for the treatment of epilepsy, but that was judged by the company to be too small a market to make the drug a "blockbuster." Accordingly, Parke-Davis (subsequently acquired by Pfizer) embarked upon a scheme to increase Neurontin® sales by promoting it for medical conditions such as pain, bipolar disorder, seizures, attention deficit disorder, migraines, and several other conditions. Although the FDA never approved Neurontin® as safe and effective for any of these conditions, physicians are free to prescribe a drug for non-approved or "off-label" use. Pharmaceutical companies, however, are barred from promoting a drug for purposes not approved by the FDA.[1] To get around this restriction, Parke-Davis concealed and misstated some clinical information about Neurontin's ability to treat these off-label conditions, sponsored ghostwritten medical articles, and paid physicians millions of dollars to promote Neurontin® for off-label uses.

On May 11, 2004, Pfizer entered into a settlement with the government where it agreed to plead guilty to criminal wrongdoing in the off-label promotion of Neurontin® and to pay $430 million. While this amount is more than a slap on the wrist, some studies have found that more than 90 percent of Neurontin® prescriptions were for off-label uses and that Neurontin® sales have regularly exceeded $1 billion a year. With bipolar disorder, for example, scientifically valid studies have found that Neurontin® does *nothing*. Some studies of bipolar disorder even found that the placebo (sugar

pill) was more effective than Neurontin. But even today, many months after the criminal plea, some physicians continue to prescribe Neurontin® for bipolar disorder. For many other conditions, Neurontin® remains safe and effective only for the manufacturer's bottom line. Pfizer currently faces a number of class action lawsuits for both its scheme to promote Neurontin for off-label uses and for the other tactics it used to block generic competition.

Vioxx® (Merck & Company)

In August 2004, an FDA researcher and other scientists working on research sponsored by Kaiser Permanente reported that Vioxx, Merck's arthritis drug, could be responsible for as many as 27,000 heart attacks. For years, Merck had insisted that the cardiovascular risks were small and that the evidence on those risks was inconclusive while it aggressively marketed the drug to consumers through television and print advertising. In September 2004, however, Merck withdrew Vioxx from the market. *The Wall Street Journal* has reported that internal company e-mails and documents show that Merck researchers recognized the increased risk of cardiac events years before the drug was recalled. But because Vioxx was a blockbuster drug with $2.5 billion in annual sales, Merck seemed willing to take this risk. Merck is now enmeshed in a multitude of legal actions arising out of the Vioxx recall.

Norvir® (Abbott Laboratories)

Abbott's Kaletra is one of several protease inhibitors used to treat HIV. Abbott also produces Norvir, which was originally developed as a protease inhibitor, but serious side effects prevented Norvir from ever being successfully marketed for that purpose. However, small doses of Norvir were found to dramatically improve blood levels of other protease inhibitors, decreasing the side effects associated with those drugs and "boosting" the antiviral effect of protease inhibitors against even resistant strains of HIV. Norvir thus became recognized as indispensable for use with virtually all protease inhibitor therapies.

Kaletra, like nearly all protease inhibitors, depends on the boosting properties of Norvir. But Kaletra was drastically losing market share to protease inhibitors manufactured by other companies. On December 3, 2003, barely five weeks after the release of GlaxoSmithKline's Lexiva and more than seven years after Norvir's introduction into the market, Abbott abruptly announced that it was raising the wholesale price of Norvir from $205.74 to $1,028.71 for 120 100 mg capsules—*an increase of more than 400 percent.* Abbott therefore drastically increased the cost of all regimens that used Norvir to boost the effectiveness of protease inhibitors. The annual cost of the Norvir needed to boost these drugs increased by $6,258 per year for protease inhibitors such as Lexiva, which requires twice-daily doses of Norvir. For Tipranovir, a protease inhibitor currently in development by Boehringer-Ingelhein, the price of the optimal Norvir booster dose would increase by more than $12,000 per year. There was one exception—Abbott did not raise the price of the Norvir used with its own Kaletra, even though patients face health risks if they switch their treatment in mid-course.[2]

On November 12, 2004, a class action lawsuit challenging the price increase in Illinois state court was dismissed.[3] The court held that the patent for Norvir essentially entitled Abbott to charge any price it wished.

Recent Class Action Lawsuits Alleging Collusive and Anticompetitive Practices by Drug Manufacturers to Block Competition

Over the last decade, there have been numerous lawsuits involving allegations that drug manufacturers, in order to illegally delay the market entry of generic competitors, have manipulated the complex laws and regulations related to the patent and drug approval processes. Several of these cases are summarized below. We begin with a brief review of the maze of laws governing the patent and drug approval process in order to understand how drug manufacturers have been able to manipulate that processes.

Background on the Drug Approval and Patent Process: How Drug Patent Holders Manipulate the System

The Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act (Hatch-Waxman), which were passed in 1984,[4] were designed to expedite the approval of generic drugs and encourage growth in the generic drug industry. To achieve this goal, Hatch Waxman shortened the generic drug approval process. Prior to Hatch-Waxman, as part of the FDA's generic drug application process, generic manufacturers were required to repeat clinical studies that had been conducted by the brand-name manufacturer when the drug was initially approved. Under Hatch-Waxman, generic manufacturers could file an Abbreviated New Drug Application (called an ANDA) with the FDA, and the ANDA could incorporate data that the brand-name drug manufacturer had already submitted to the FDA. Therefore, the generic manufacturer had to show only that its drug was "therapeutically equivalent" (the same chemical compound, absorbed by the body in the same way as the brand-name drug) to the brand-name drug.

Although Hatch-Waxman did spur growth in the generic drug industry, drug manufacturers have abused some unique provisions of the Act to stall generic competition. These provisions—or loopholes—in the Hatch-Waxman Act are outlined briefly below and are the basis of many ongoing lawsuits against drug manufacturers. Some of these loopholes were closed by provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), passed in December 2003.

■ The ANDA Patent Challenge Procedure

This section outlines the laws and regulations related to the drug approval process prior to the passage of the MMA. All of the lawsuits outlined in this document are based on actions that occurred before passage of the MMA.

Where the Patent Process and the Drug Approval Process Meet

The FDA publishes a guide referred to as The Orange Book that lists all of the prescription drugs approved for use in the U.S and the patents covering those drugs.[5] When a pharmaceutical manufacturer receives a patent related to a brand-name drug, it submits that patent information for inclusion in The Orange Book. The FDA does not conduct any separate review of the patents submitted.

When a generic manufacturer files an Abbreviated New Drug Application (ANDA) for approval of a generic, as part of its application, it must make one of four certifications to the FDA regarding each patent the brand-name manufacturer has submitted to The Orange Book. These certifications are as follows: (i) there are no patent data listed in The Orange Book; (ii) the relevant patents have expired; (iii) the generic manufacturer is asking for approval to market only after the listed patents expire; and (iv) there is a patent on the drug listed in The Orange Book, but that patent is either invalid or will not be infringed by the marketing of the generic.[6] It is this last type of certification, referred to as a "Paragraph IV Certification," that has been manipulated by drug manufacturers to extend monopolies of brand-name drugs.

- **How Paragraph IV Certifications Have Been Used to Extend Brand-Name Drug Monopolies**

  When a generic manufacturer files a Paragraph IV Certification with the FDA, it must notify the patent holder (for simplicity, referred to here as the brand-name drug manufacturer). The brand-name drug manufacturer then has 45 days from the date of the notice to file a lawsuit for patent infringement. The mere filing of such a lawsuit will automatically delay approval of the generic for 30 months (referred to as the "30-month stay") *unless* the patent expires in the meantime or there is resolution of the lawsuit. Although filing an ANDA with a Paragraph IV certification leaves a generic manufacturer open to the risk of a patent infringement lawsuit, filing a generic drug approval application with a Paragraph IV Certification is not without potential rewards. The first generic manufacturer that files an ANDA with a Paragraph IV certification is eligible for 180 days of market exclusivity; during this 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.[7]

- **How Manufacturers Manipulate the Drug Approval Process to Extend Patents**

  Despite the goal of Hatch Waxman to expand consumer access to generics, the combination of The Orange Book listing requirements, the 30-month stay, and the exclusivity period presented crafty brand-name manufacturers with numerous opportunities to extend their monopolies by using a variety of anticompetitive tactics. Below we discuss how brand-name manufacturers used each of these "loopholes" to game the system and extend their monopolies.[8]

  - ***Orange Book Listing and the 30-Month Stay***: As discussed above, brand-name manufacturers can delay generic competition by simply filing a patent infringement lawsuit within 45 days of notice that a generic manufacturer has filed an application with a Paragraph IV Certification. Therefore, there is an incentive for brand-name manufacturers to claim, obtain, and list as many patents as possible—essentially keeping an ongoing list of active patents in The Orange Book. This forces any generic drug manufacturer to file a Paragraph IV certification with their approval application, to which the brand-name drug manufacturer responds by quickly filing a patent infringement

lawsuit, thus delaying generic market entry for up to 30 months. If, during this process, the brand-name drug company acquired and listed a new patent, the generic applicant would have to submit another Paragraph IV certification, thus starting the process all over and giving rise to another 30-month stay.

NOTE: *The MMA limited this "loophole" in the Hatch-Waxman Act by assuring that brand-name manufacturers can now claim only one 30-month stay.[9] The MMA's amendments to Hatch-Waxman now require that generic ANDA applicants make Paragraph IV certifications only to patents that were listed in The Orange Book at the time the ANDA was filed.[10]*

- ***Exclusivity Period:*** The exclusivity period, which gives the first generic applicant filing a Paragraph IV Certification 180 days of market exclusivity, has allowed generic manufacturers to control the timing of generic competition.[11] Because FDA final approval does not require a company to market a drug commercially, the first ANDA filer to win approval could delay marketing as long as it liked—the FDA could not grant approval to other generic drugs until the first filer received its 180 days.[12]

  Creative—but potentially illegal—partnerships between the generic manufacturer 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 were sometimes shared with the generic manufacturer (either cash payments or through participation in the brand-name monopoly) in exchange for agreeing not to go to market with the generic product.[13]

  NOTE: Under the MMA, generic manufacturers can no longer "sit" on the exclusivity period indefinitely to block FDA approval of subsequent applicants. The MMA's changes to the Hatch-Waxman Act now include "forfeiture events" through which the first applicant can lose its claim to the 180-day exclusivity period.[14] Moreover, and perhaps most importantly, pharmaceutical industry collusion will now be subjected to more rigorous scrutiny by federal regulators. As recommended by a Federal Trade Commission (FTC) study,[15] Section 1112 of the MMA requires that agreements between brand-name and generic manufacturers be submitted for review by the FTC and Department of Justice.

■ Implications of the Changes Made to Hatch-Waxman by the New Medicare Drug Law

In the area of drug approvals, at least, the MMA has made laudable progress in preventing and deterring some of the more abusive practices used by the brand-name drug industry. However, even with the changes in the MMA, there is still room for abuse, so there remains a continued need for industry monitoring, consumer vigilance, and legislative solutions. Brand-name manufacturers are still "rewarded" for claiming as many patents as they can (the weak as well as the strong), listing them in The Orange Book, and promptly bringing patent infringement suits against Paragraph IV ANDA filers (generic manufacturers). These rewards come in the form of millions of dollars in profits resulting from forestalling generic competition, regardless of the ultimate outcome of the patent infringement lawsuits.

The following listings summarize the allegations and status of several recent or pending class action lawsuits that allege unlawful collusive or anticompetitive practices by drug manufacturers. These case summaries are intended to provide a brief sketch of the drug industry's anticompetitive practices that were recently the subject of litigation. **This is not an exhaustive list of all litigation related to drug industry anticompetitive practices**. Upon request, Families USA can provide more detailed information about these cases and about the drug industry in general.

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[1] See 21 U.S.C. §§ 331(z), 360aaa, *et seq*.

[2] Abbott developed Norvir with the assistance of a National Institutes of Health grant and spent only approximately $15 million of its own funds on pre-approval clinical trials for the drug. By the end of 2001, Norvir had generated cumulative sales for Abbott of more than $1 billion (more than 60 times the estimated cost of its pre-approval outlays). Even without the exorbitant price increase, Norvir would likely generate more than $2 billion for Abbott over the next 10 years.

[3] Gingreau v. Abbott Laboratories, No. 04 CH 8202, Memorandum and Order (Cook County Circuit Court, Nov. 12, 2004).

[4] 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. A more complete discussion of Hatch-Waxman and the drug approval process is covered in a companion piece, *Overview of Hatch Waxman: Legislative Background* (Washington: Families USA, April 2002).

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

[6] 21 U.S.C. § 355(j)(2)(A)(vii).

[7] 21 U.S.C. § 355(j)(5)(B).

[8] *See* Herbert Hovenkamp, Mark Janis, Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn L. Rev. 1719, 1752 (June 2003). "Each of these affects the bargaining dynamic in modern pioneer/generic pharmaceutical patent litigation, and each can be criticized as presenting opportunities for either unilateral anticompetitive behavior on the part of the pioneer or pioneer/generic collusion in the form of anticompetitive settlements."

[9] See 21 U.S.C. § 355(j)(2)-(5).

[10] See Barry L Marenberg, *Changes to the Hatch-Waxman Act Following the "*Medicare Prescription Drug, Improvement and Modernization Act of 2003", 23 *Biotechnology L. Rep. 277* (June 2004).

[11] 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."

[12] David A. Balto, "Pharmaceutical Patent Settlements: The Antitrust Risks" *55 Food & Drug Law Journal*, 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."

[13] Ibid.

[14] See 21 U.S.C. § 355(j)(5).

[15] The FTC conducted a study of agreements between pioneer drug manufacturers and generic producers that were designed to block the introduction of generic drugs and issued a report in July 2002. See *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available online at http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm.

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Pharmaceutical Class Action Summaries

ATIVAN AND TRANXENE 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

Market Background

Class Period: January 1, 1998 through December 31 , 1999

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 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 more than 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). See settlement Web site: www.mylansettlement.com. On June 16, 2003, the court approved a settlement in the amount of $35 million for the Direct Purchaser Class. *In re Lorazepam & Clorazepate Antitrust Litig.*, 2003-1 Trade Cas. (CCH) ¶74,134 (D.D.C. June 16, 2003).

AUGMENTIN LITIGATION

Litigation Background

Courts:	United States District Court for the District of Virginia
Plaintiffs:	Indirect purchasers (consumers and third party payors)
Defendants:	GlaxoSmithKline PLC and SmithKline Beecham Corporation
Class Period:	4, 2000 through April 30, 2004

Market Background

Drug:	Brand name: Augmentin®; Generic name: amoxicillin clavulanate potassium
Indication:	Treatment of lower respiratory, middle ear, sinus, skin, urinary tract, and other bacterial infections
Market Size:	$1.3 billion (2001)
ANDA filers:	Geneva Pharmaceuticals, Inc., Teva Pharmaceuticals USA Inc., and Ranbaxy Pharmaceuticals, Inc.
Is generic now on the market?	Yes

Underlying Allegations

The actions allege that GlaxoSmithKline misled the United States Patent Office into issuing patents to protect Augmentin® from competition from generic drug substitutes. GlaxoSmithKline then allegedly used the protection of those patents to keep generic versions of Augmentin® off the market.

Status

Following an October 28, 2004 fairness hearing, the court approved a $29 million settlement. See settlement Web site: www.augmentinlitigation.com.

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

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 defendants' 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). Early last year, a settlement for the Direct Purchaser Class in the amount of $220 million was approved by the court. On November 14, 2003 the court granted final approval to an Indirect Purchaser Class settlement. This settlement is divided into a Consumer Fund and an Agency Account. The settlement amount, plus a contribution from the settlement of related litigation, brought the total Consumer Fund to approximately $41.7 million. The Agency Account totalled approximately $63.5 million for the benefit of government entities. Additionally, this settlement provided for injunctive relief against Bristol-Myers Squibb for a 10-year term. See settlement Web site: www.busparsettlement.com.

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

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 trial 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). On June 13, 2003, a panel of the United States Court of Appeals for the Sixth Circuit affirmed the grant of partial summary judgment in favor of plaintiffs. *In re Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S.Ct. 307 (2004). The trial court certified a class of direct purchasers, *In re Cardizem CD Antitrust Litig.,* 200 F.R.D. 297 (E.D. Mich. 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) (address-

Status (continued)

ing 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. On October 1, 2003, Judge Edmunds granted final approval to an $80 million settlement for the benefit of third-party payors and consumers. *In re Cardizem CD Antitrust Litig.,* 218 F.R.D. 508 (E.D. Mich. 2003). See settlement Web site: www.cardizemsettlement.com. An appeal from the judgment approving the settlement remains pending in the Sixth Circuit. The individual actions of several opt-out plaintiffs remain pending in the trial court.

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: $1.8 billion (2001)

***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? yes

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). On May 20, 2003, the court granted, in part, and denied, in part, the defendants' motions to dismiss, and denied plaintiffs' motions for partial summary judgment. *In re Ciprofloxacin Antitrust Litig*., 261 F. Supp. 2d 188 (E.D.N.Y. 2003). In actions pending in California state court, dismissal motions have been denied and a state-wide class has been certified. See *In re Cipro Cases I & II*, 121 Cal. App. 4th 402, 17 Cal. Rptr. 1 (4th Dist. 2004); See also case Web site: www.california-cipro-litigation.com. Defendants' summary judgment motions remain pending in both the California litigation and the federal litigation.

HYTRIN LITIGATION

In re Terazosin Hydrochloride Antitrust Litigation

Litigation Background

Court: United States District Court for the Southern District of Florida (coordinat ng 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 Phar maceuticals, 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 trial court granted partial summary judgment in favor of plaintiffs and found that Abbott's agreements with Zenith Goldline and Geneva Pharmaceuticals were *per se* illegal under federal and state antitrust law. *In re Terazosin Hydrochloride Antitrust Litig*., 164 F. Supp. 2d 1340 (S.D. Fla. 2000). On September 15, 2003, the United States Court of Appeals for the Eleventh Circuit reversed, rejecting the conclusion that the agreements were *per se* unlawful. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc*., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 125 S.Ct. 308 (2004). The Eleventh Circuit expressly disagreed with the Sixth Circuit's holding to the contrary in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (*see* page 11, *supra*). The trial court had also granted a motion to certify a class of direct

Status (continued)

purchasers. *In re Terazosin Hydrochloride Antitrust Litig.,* 203 F.R.D 551 (S.D. Fla. 2001). On November 14, 2003, however, the Eleventh Circuit vacated class certification and remanded for further proceedings. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc*., 350 F.3d 1181 (11th Cir. 2003). On remand, the motion to certify a direct purchaser class was denied. *In re Terazosin Hydrochloride Antitrust Litig.,* 223 F.R.D 666 (S.D. Fla. 2004). On April 8, 2004, the court certified a multistate indirect purchaser class. *In re Terazosin Hydrochloride Antitrust Litig.,* 220 F.R.D 672 (S.D. Fla. 2004). That decision is the subject of an interlocutory appeal in the Eleventh Circuit. On August 31, 2004, the court granted defendants' motion for summary judgment on part of the case. *In re Terazosin Hydrochloride Antitrust Litig.,* 335 F. Supp. 2d 1336 (S.D. Fla. 2004).

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 Laborato ries, 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

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). On December 8, 2003, the full Commission reversed and vacated the administrative law judge's decision, holding that the agreement was anticompetitive and issuing a cease and desist order. *In the Matter of Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003). The class action lawsuits are in the initial stages of litigation. On September 29, 2004, the court denied the defendants' motions to dismiss. *In re K-Dur Antitrust Litig*., 338 F. Supp. 2d 517 (D.N.J. 2004).

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: Indirect purchasers (consumers and third-party payors)

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 acetate

Indication: A gonadotropin releasing hormone (GnRH) agonist used to treat en dometriosis that may also be used to treat prostate cancer and other con ditions 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 copayments 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 of the cost, is proceeding with discovery. On Nov. 25, 2003, the federal court granted in part and denied in part defendants' motions to dismiss. *In re Lupron Marketing and Sales Practices Litig*., 295 F. Supp. 2d 148 (D. Mass. 2003). State courts have granted class certification motions in New Jersey, North Carolina, and Illinois. *See, e.g., Clark v. TAP Pharmaceutical Products, Inc*., 343 Ill. App. 3d 538, 798 N.E. 2d 123 (2003). On November 24, 2004, the federal court granted preliminary approval to a proposed $150 million settlement with TAP. A final approval hearing is scheduled for April 13, 2005. See settlement Web site: www.lupronclaims.com.

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

NEURONTIN LITIGATION

(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: $1.4 billion (2001)

Brand-Name Manufacturer: Pfizer, Inc.

ANDA Challenging Patent(s): Purepac Pharmaceuticals, Inc. and Apotex Corp.

Is generic now on the market? Yes

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 been transferred by the Judicial Panel on Multidistrict Litigation (MDL) to the United States District Court for the District of New Jersey. In May 2004, a *qui tam* action pending in the United States District Court for the District of Massachusetts captioned *United States ex rel. Franklin v. Parke-Davis, Warner Lambert and Pfizer*, No. 96-cv-11651-PBS (D. Mass.) was fully unsealed. The *qui tam* action detailed the defendants' scheme to illegally promote Neurontin for purposes that have not been approved by the FDA. On May 11, 2004, Pfizer entered into a settlement agreement and release with the government wherein it agreed to plead guilty to criminal wrongdoing in the off-label promotion of Neurontin and pay a settlement of $430 million. A number of class actions concerning the off-label use have been transferred by the MDL to the District of Massachusetts.

NOLVADEX LITIGATION

In re Tamoxifen Citrate Antitrust Litigation

Litigation Background

Court:	United States District Court for the Eastern District of New York (coordi nating 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?	Yes

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). On May 15, 2003, the court granted the defendants' motion to dismiss. *In re Tamoxifen Citrate Antitrust Litig*., 277 F. Supp. 2d 121 (E.D.N.Y. 2003). The decision has been appealed to the United States Court of Appeals for the Second Circuit.

OXYCONTIN LITIGATION

Litigation Background

Court: United States District Court for the Southern District of New York and a number of state courts

Plaintiffs: Direct purchasers (drug wholesalers), indirect purchasers (consumers and third party payors)

Defendants: Purdue Pharma L.P.

Class Period: December 1995 to the present

Market Background

Drug: Brand name: Oxycontin®; Generic name: oxycodone hydrochloride

Indication: Used to treat moderate to severe pain

Market Size: $1.3 billion (2003)

ANDA Filers: Endo Pharmaceuticals, Inc., Teva Pharmaceuticals, IMPAX Laboratories, Inc.

Is generic now on the market? Yes

Underlying Allegations

Plaintiffs allege that Purdue Pharma L.P unlawfully obtained and maintained a monopoly on controlled-release oxycodone hydrochloride prescription tablets by a series of unlawful actions that enabled it to receive patents related to oxycodone hydrochloride. Plaintiffs allege that, in the absence of Purdue's unlawful and inequitable actions, generic versions of OxyContin could have been available for sale as early as December 1995.

Status

On January 5, 2004, the United States District Court for the Southern District of New York held that the patents at issue were rendered unenforceable by virtue of Purdue's inequitable conduct before the Patent and Trademark Office. *See Purdue Pharma L.P. v. Endo Pharms. Inc.*, 70 U.S.P.Q.2d 1185 (S.D.N.Y. Jan. 5, 2004). An appeal from that judgment is pending. The class action lawsuits remain in their initial stages.

PAXIL LITIGATION

Litigation Background

Court: United States District Court for the Eastern District of Pennsylvania

Plaintiffs: Direct purchasers (drug wholesalers), 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 depres sion and other mental illnesses

Market Size: $2.3 billion (2003)

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? Yes

Underlying Allegations

Plaintiffs allege that 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. On October 18, 2004, the court granted preliminary approval to a $65 million settlement for indirect purchasers. A final approval hearing is scheduled for March 9, 2005. See settlement Web site: www.paxilclaims.com. On November 3, 2004, the court granted preliminary approval to a $150 million settlement for direct purchasers. A final approval hearing is scheduled for January 27, 2005.

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: An estrogen hormone used to supplement estrogen levels when the body no longer produces enough. It is also used to help prevent osteoporosis (weak ened 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 of 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 benefit 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. The court has denied the motion to dismiss the direct purchaser case and granted the motion to certify the direct purchaser class. *See JBDL Corp. v. Wyeth Ayerst Laboratories Inc*., __ F. Supp. 2d __ 2003 WL 23844777 (S.D. Ohio May 12, 2003) (certifying direct class). In separate orders issued on June 30, 2004, the court granted in part and denied in part the motion to dismiss the indirect class, and granted in part and denied in part the motion to certify the indirect purchaser class. The court provisionally certified an indirect purchaser class covering purchases in 18 states. In a separate action pending in California state court, a state-wide class was certified on July 19, 2004.

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

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. *Mylan Pharmaceuticals, Inc. v. Thompson*, 207 F. Supp.2d 476 (N.D.W.Va. 2001). The court has granted defendants' motions to dismiss three class actions and granted, in part, and denied, in part, motions to dismiss two class actions. The class actions were dismissed following the court's denial of plaintiffs' motion for class certification.

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 ar thritis

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., Geneva Pharmaceuticals, Inc.

Is generic now on the market? Yes

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 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. *In re: '639 Patent Litigation*, 154 F. Supp. 2d 157 (D. Mass. 2001), *aff'd sub. nom SmithKline Beecham Corp. v. Copley Pharmaceutical, Inc.*, 45 Fed. Appx. 915 (Fed. Cir. Aug 15, 2002), *rehearing and rehearing en banc denied* (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.

Status

Several class action lawsuits have been coordinated in the United States District Court for the District of Massachusetts. On October 1, 2003, the Court denied defendants' motions to dismiss and held that defendants were bound by certain factual findings from the patent litigation. *In re Relafen Antitrust Litig*., 286 F Supp. 2d 56 (D. Mass. 2003). On October 29, 2003, the court granted a motion to certify the Direct Purchaser Class. *See In re Relafen Antitrust Litig.*, 218 F.R.D. 337 (D. Mass. 2003). On November 21, 2003, the court certified an exemplar or model end-payor class that included consumers and third party payors in Arizona, California, Massachusetts, Tennessee, and Vermont. See *In re Relafen Antitrust Litig*., 221 F.R.D. 260 (D. Mass. 2004). On April 2, 2004, the court approved

RELAFEN LITIGATION (continued)

Status (continued)

a $175 million class action settlement for direct purchasers. On November 24, 2004, the court granted preliminary approval to a proposed $75 million settlement for indirect purchasers. A final approval hearing is scheduled for May 2, 2005. See settlement Web site: www.relafensettlement.com. On November 29, 2004, the court issued an opinion regarding its previous order granting in part and denying in part defendants' motions for summary judgment. *In re Relafen Antitrust Litig.*, __ F. Supp. 2d __, 2004 WL 2750101 (D. Mass. Nov 29, 2004).

TAXOL LITIGATION

Litigation Background

Courts: United States District Court for the District of Columbia

Plaintiffs: Direct purchasers (drug wholesalers), 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's 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's 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. A final order approving the $65 million direct purchaser class settlement was entered on August 15, 2003. A final order approving the $15.2 million third-party payor class settlement was entered on October 22, 2003. On November 19, 2003, the court granted final approval to a $50 million indirect purchaser class settlement for the benefit of consumers and state agencies. See settlement Web site: www.taxolsettlement.com. See also *VistaHealth Plan, Inc. v. Bristol-Myers Squibb Co.*, 287 F. Supp. 2d 65 (D.D.C. 2003).

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? Yes

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, lnt. 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.

WELLBURTRIN SR/ZYBAN LITIGATION

Litigation Background

Court: United States District Court for the Eastern District of Pennsylvania

Plaintiffs: Direct purchasers (drug wholesalers), indirect purchasers (consumers and third party payors); state attorneys general

Defendant: SmithKline Beecham Corporation, GlaxoSmithKline plc

Class Period: January 24, 2002 through date to be determined

Market Background

Drug: Brand name: Wellbutrin SR®/Zyban®; Generic name: bupropion hydro chloride

Indication: An antidepressant in a sustained form used to treat depression; also pre scribed under the name Zyban® as a smoking cessation aid

Market Size: $1.7 billion (2003)

Brand-Name Manufacturer: SmithKline Beecham Corporation

First Filer of ANDA Challenging Patent(s): Andrx Pharmaceuticals Inc.

Subsequent ANDA Filers: Excel Pharmaceuticals Inc., Impax Laboratories, Inc., Eon Labs Manufactur ing and Watson Pharmaceuticals

Is generic now on the market? Yes

Underlying Allegations

Plaintiffs allege that GlaxoSmithKline extended its monopoly of Wellbutin SR® and Zyban® by making fraudulent assertions to the United States Patent and Trademark Office during patent prosecution and initiating repeated sham litigation with the intent of delaying and preventing generic manufacturers from entering the market for sustained release bupropion.Since August 1999, five generic companies submitted ANDAs including Paragraph IV certifications for generic Wellbutrin SR®, and all were sued by the defendant for patent infringement.After years of litigation between GSK and the generic manufacturers, EON's Wellbutrin SR® ANDA was the first to receive final approval after the 30-month stay expired in November 2003.After EON announced the product would be marketed, GSK further delayed the introduction of generic Wellbutrin SR® by obtaining an injunction in the United States District Court for the Southern District of New York in November, 2003. EON appealed the injunction to the Federal Circuit and it was stayed on January 14, 2004. If not for the 30-month stay invoked under Hatch Waxman by GSK filing baseless EON litigation and the additional period of exclusivity gained for GSK by obtaining an improper injunction, EON would have been able to market generic Wellbutrin SR® on January 24, 2002, nearly two years earlier than they actually began marketing the drug. Plaintiffs and the class paid supracompetitive prices due to defendants' monopolization of Wellbutrin SR®.

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 are in the initial stages of litigation.

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