

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE NEXIUM CONSUMER/PAYOR
ADVERTISING LITIGATION

Master File No. 1:05-cv-75

Hon. Sue L. Robinson, USDJ

This document relates to: All Actions

CONSOLIDATED CLASS ACTION COMPLAINT

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Plaintiffs allege upon personal knowledge as to their own acts, and upon information and belief (based on the investigation of counsel) as to all other matters, as to which allegations Plaintiffs believe substantial evidentiary support will exist after a reasonable opportunity for further investigation and discovery as follows:

I. NATURE OF THE ACTION

1. This is a class action brought against the AstraZeneca group of pharmaceutical companies for unfair and deceptive trade practices and for consumer fraud in the marketing of the brand-name drug Nexium. Plaintiffs seek injunctive relief, monetary damages, and equitable restitution under the laws of the several states.

2. Defendants AstraZeneca Pharmaceuticals LP and Zeneca, Inc. ("AstraZeneca") had a patent for the drug Prilosec which by the year 2000 was the most widely prescribed drug in the world, with annual sales in excess of \$6 billion. Prilosec, long-advertised as "the purple pill," is a proton-pump inhibitor ("PPI") or acid-pump inhibitor that is used to treat heartburn and esophageal erosions.

3. A patented drug is also referred to as a "brand name" drug. Brand name drugs which face no competition are the most profitable drugs for drug manufacturers. In the year 2000, the average retail price of a prescription drug was more than three times that of a generic drug.¹

4. The patent for Prilosec was set to expire in 2001 and AstraZeneca anticipated that it would face stiff competition from generic manufacturers. It is a fact well known to drug manufacturers that entry of generics results in a substantial loss of market share for the brand-name manufacturers, sharply reduced prices, and a decrease in profits. AstraZeneca was thus facing the loss of its most profitable drug.

¹ Kaiser Family Foundation, *Trends as Indicators in the Charges*, Health Care Marketplace 2004 Update (2004).

5. Consequently, years before the Prilosec patent was set to expire, AstraZeneca formed a group of marketers, lawyers and scientists to come up with a solution for what the company believed was a looming patent-expiration disaster. The group called itself the “Shark Fin Project” after the dismal shape the sales chart would form if they did nothing and allowed generic competition to erode Prilosec’s market share and price: an inverted V.

6. The Shark Fin Project implemented a multi-prong attack. First, it hauled generic manufacturers into court seeking to delay entry of competition. Second, shortly before the patent on Prilosec was set to expire, the company received FDA approval for a new PPI, Nexium, which was a newly patented brand name drug AstraZeneca intended to position as Prilosec’s replacement.

7. AstraZeneca knew that it could not succeed if Nexium was marketed simply as essentially the same drugs as Prilosec. To justify the difference in price between Nexium and generic Prilosec, AstraZeneca had to convince doctors and consumers that Nexium was superior to Prilosec. AstraZeneca set out to do just that. Nexium became the most heavily advertised drug in the United States. Doctors and consumers were blanketed with advertisements for a “new purple pill”: “Today’s purple pill is Nexium, from the makers of Prilosec.” Other advertisements described the “new Nexium” as the “POWERFUL NEW PPI” (emphasis in advertisement). AstraZeneca’s advertisements either implicitly or expressly represented that the new purple pill was superior. After all, why market a product as “new” if it were not somehow better than the prior version?

8. AstraZeneca’s 6,000 salespeople blitzed doctors with studies proclaiming Nexium’s superiority and urging them to “prescribe the new purple pill.” The promotional campaign reportedly cost AstraZeneca a half billion dollars in just 2001. Virtually overnight, Nexium – “the new purple pill” – began to replace Prilosec, the old “purple pill.” Eventually the company dropped all references to the older drug, Prilosec, in its advertisements.

9. However, Nexium was neither new, nor superior nor more “powerful” than existing PPIs, including Prilosec. Prilosec is comprised of an organic molecule, omeprazole, which – like most organic molecules – exists in two forms (or “isomers”) that are mirror images of each other. Prilosec is what is called a “racemic” formulation of this molecule, meaning that it is comprised of a mixture of both mirror images (so-called “S” and “R”) of this molecule. In other words, Nexium is simply Prilosec without the less active R-enantiomer. Head-to-head studies comparing Nexium and Prilosec establish they are, chemically and therapeutically, essentially the same.

10. To obtain approval for Nexium from the Food and Drug Administration (“FDA”), AstraZeneca had to test it in several clinical trials. Some of these trials merely compared Nexium with placebos to show that it worked better than nothing, since that is all the FDA requires. But four trials compared Nexium head-to-head with Prilosec and these were crucial to AstraZeneca’s marketing strategy. The Company needed to show that Nexium was better than Prilosec – an advance over the older drug.

11. Instead of seemingly comparing equivalent doses, *i.e.*, 20 milligrams (“mg”) or less of Nexium, versus the standard 20 mg dose of Prilosec recommended for most indications, the Company included higher doses of Nexium in its studies. AstraZeneca compared Nexium 40 mg to Prilosec 20 mg. With the studies skewed in this way, AstraZeneca expected Nexium to show a significant improvement over Prilosec. This did not happen. As the FDA repeatedly noted in its review of Nexium’s New Drug Application (“NDA”), the submitted studies comparing Nexium to Prilosec “do[] not lead to the conclusion that [Nexium] is superior to omeprazole [Prilosec]....”

12. Despite its failure to prove Nexium’s superiority over Prilosec, AstraZeneca nevertheless promoted Nexium to doctors and consumers as the “first proton pump inhibitor (PPI) to offer significant clinic improvements over Losec [*i.e.* Prilosec] and its main competitor,

lansoprazole, in terms of acid control and clinical efficacy.”² It also claimed that Nexium was more effective in acid inhibition than other comparable drugs and provided relief in a shorter period of time. AstraZeneca repeated these messages in a steady stream of marketing directed to patients and doctors.

13. AstraZeneca’s campaign worked, with sales of Nexium sky rocketing to reach \$3.3 billion by 2003.

14. The truth, however, is that there are no clinical improvements that Nexium offers over Prilosec. The drug was created and promoted solely to maintain AstraZeneca’s Prilosec profit stream and not because it offers any medical benefits not available from use of Prilosec or other PPIs. As the FDA reviewers found, “superiority of Nexium over omeprazole was not demonstrated.” For consumers, Prilosec is just as effective and at far less cost. As noted by the former administrator of the federal Centers for Medicare and Medicaid services (“CMS”), Thomas Scully, at a convention of the American Medical Association: “You should be embarrassed if you prescribe Nexium because it increases costs with no medical benefits.”³ Mr. Scully noted, “[t]he fact is Nexium is Prilosec ... [i]t is the same drug. It is a mirror compound.”⁴ Mr. Scully further stated that “Nexium is a game that is being played on the people who pay for drugs.”⁵ A pharmaceutical industry analyst, in reacting to the recent news that the Pentagon will no longer pay for Nexium, noted “Nexium is not worth the money period.... [Its pretty dubious to pay \$4 a pill for Nexium when you can get over-the-counter Prilosec for 67 cents.”⁶ Unfortunately, as a result of Defendants’ promotional and sales practices, billions have been spent on Nexium which should not have been.

² AstraZeneca Annual Report Form 20-F-2000 at p. 11.

³ NEW YORK TIMES, April 21, 2003.

⁴ *Id.*

⁵ *Id.*

⁶ Pentagon to Drop Nexium From Its List of Covered Drugs For Military Personnel, WASHINGTON POST, May 8, 2005 at A6.

15. In this action, Plaintiffs seek restitution and equitable relief arising out of AstraZeneca's sale and promotion of Nexium pursuant to practices and acts that are unfair, deceptive and unlawful in violation of state laws.

II. PARTIES

16. Plaintiff Pennsylvania Employees Benefit Trust Fund ("PEBTF") is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 150 South 43rd Street, Suite I, Harrisburg, Pennsylvania 17111-5700. PEBTF provides comprehensive healthcare benefits, including prescription drug coverage, to 70,000 participants and beneficiaries, which includes active and retired employees of the Commonwealth of Pennsylvania, as well as their spouses and dependents. A number of participants and beneficiaries of PEBTF live in Delaware as well as in Pennsylvania and other states. During the Class Period as described herein, PEBTF paid for some or all of the purchase price of Nexium prescribed to one or more of its participants or beneficiaries, and has thereby been injured, and continues to be injured, as a result of Defendants' conduct.

17. Plaintiff Linda A. Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan ("Wellness Plan") and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc. ("OmniCare") is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private third party payers Wellness Plan and OmniCare. During the Class Period as described herein, Wellness Plan and OmniCare were private third-party payers whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in their plan. During the Class Period as described herein, Wellness Plan and OmniCare paid for prescriptions of Nexium and thereby have been injured by Defendants' conduct.

18. Plaintiff AFSCME District Council 47 Health & Welfare Fund ("AFSCME") is a welfare benefit plan duly organized under the laws of Pennsylvania. It is located at 1606 Walnut

Street, Philadelphia, Pennsylvania. Its members include roughly 4,000 active city employees and 700 retirees. During the Class Period as described herein, AFSCME paid for some or all of the purchase price of Nexium prescribed to one or more of its participants and has been injured by Defendants' conduct.

19. Plaintiff Joseph Macken is an individual residing in East Meadow, Nassau County, New York. During the Class Period described herein, Plaintiff purchased Nexium for his own consumption and was injured as a result of Defendant's conduct alleged herein.

20. Plaintiff Victoria Scofield is a resident of Wrightsville, Pennsylvania. She took Nexium until the summer of 2004 and by virtue of making co-payments for Nexium was injured as a result of Defendants' unlawful conduct alleged herein.

21. Plaintiff Janet McGrorty is a resident of Reno, Nevada. She has taken Nexium since 2002 and by virtue of making co-payments for Nexium was injured by the unlawful conduct alleged herein.

22. Plaintiff Richard Tikkuri is an individual residing at Cudahy, Wisconsin. He has taken Nexium since 2004 and by virtue of making co-payments for Nexium was injured by the unlawful conduct alleged herein.

23. Wisconsin Citizen Action ("WAC") is a nonprofit corporation with its headquarters located in Madison, Wisconsin. WAC is the state's premier public interest organization dedicated to social, economic and environmental justice for all. It has as one of its goals working to provide quality, affordable health care for all. Its members have used and paid for Nexium and have been injured by the unlawful conduct alleged herein.

24. United Senior Action of Indiana is a nonprofit organization devoted to issues affecting seniors including affordable health care. Its members have purchased Nexium and been damaged by the unlawful conduct alleged herein.

25. Plaintiff North Carolina Fair Share is a statewide, multi-issue, non-profit corporation located in Raleigh, North Carolina. It has as one of its goals helping the low wealth,

unemployed and underemployed. Its members have used and paid for Nexium and have been injured by the unlawful conduct alleged herein.

26. Defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. Zeneca is a wholly owned subsidiary of AstraZeneca Group PLC, a limited liability company domiciled in the United Kingdom.

27. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is owned and controlled by AstraZeneca Group PLC, a public limited liability company domiciled in the United Kingdom.

28. Zeneca and AstraZeneca Pharmaceuticals LP are collectively referred to as "AstraZeneca."

29. AstraZeneca maintains research and development and manufacturing facilities worldwide, including in the United States. AstraZeneca reported annual sales of \$18.8 billion in 2003, with an operating profit of \$4.2 billion. Its 2003 sales of Nexium were \$3.3 billion, or 17% of all sales.

III. JURISDICTION AND VENUE

30. This Court has diversity subject-matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, as here, "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the aggregated amount in controversy exceeds five million dollars (\$5,000,000). *See* 28 U.S.C. § 1332(d)(2) and (6). This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and Defendants systematically and continually conduct business throughout the State of Delaware, including marketing, advertising, and sales directed to Delaware residents.

31. Venue is proper here in that Defendants are incorporated and/or have their principal places of business within the District, Defendants engaged in substantial conduct relevant to the claims within this District, and Plaintiffs suffered substantial loss for purchases of Nexium made within this District.

IV. FACTUAL ALLEGATIONS

A. Prilosec – A Blockbuster Drug for AstraZeneca

32. Prilosec (also known as Losec) is a proton-pump inhibitor (“PPI”). According to AstraZeneca’s publicly filed documents, by the year 2000 Prilosec had “set a new global standard in short and long-term treatment of acid related diseases.” According to AstraZeneca’s publicly filed documents, Prilosec had benefited patients in 530 million patient treatments since 1980 and “is the world’s largest selling pharmaceutical.” Prilosec was AstraZeneca’s most profitable drug with worldwide sales of over \$6 billion by 2000.⁷

33. PPIs are used to treat the three gastroesophageal reflux disease (“GERD”) indications that require gastric acid inhibition. These three indications are: treatment of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic GERD.

34. Erosive esophagitis is related to heartburn. Heartburn is a gastrointestinal condition caused by acid backflow from the stomach to the esophagus, the swallowing tube from the mouth to the stomach. Normally, a muscular valve at the lower end of the esophagus keeps acid in the stomach and out of the esophagus. When the valve relaxes too frequently, stomach acid flows backward into the esophagus, causing a burning sensation in the chest and throat. This is commonly known as “heartburn” or acid indigestion.

35. More than 60 million Americans experience heartburn/acid indigestion at least once a month, and some studies suggest that more than 15 million Americans experience heartburn/acid indigestion daily. Symptoms are more common among the elderly and pregnant women and can last for several hours, often worsening after eating. Frequent heartburn (two or

⁷ 2001 Annual Report at p. 38.

more episodes per week) may be associated with a more severe condition known as gastroesophageal reflux disease or GERD.

36. Without effective treatment, GERD can cause serious complications such as severe chest pain, esophageal stricture (narrowing or obstruction/damage of the esophagus), bleeding, asthma-like symptoms, or Barret's esophagus (a precancerous condition of the esophagus).

37. Another possible complication of GERD/heartburn is erosive esophagitis. This condition is characterized by erosion of the lining of the esophagus caused by chronic backflow of acid from the stomach. Patients with erosive esophagitis usually have the typical symptoms of GERD. An endoscopy is required to diagnose erosive esophagitis. An endoscopy is an outpatient procedure that allows a physician to explore the esophagus and stomach using a small flexible tube with a tiny camera. Once erosive esophagitis is identified as the source of heartburn, physicians can prescribe medications to treat the symptoms and heal the esophagus.

38. Omeprazole, the active ingredient in Prilosec, is a "racemic" mixture containing S- and R-enantiomers. Enantiomers are molecules that have two non-superimposable mirror image forms, *i.e.*, a right and left hand version. Racemic mixtures, such as Prilosec, contain equal proportions of the two enantiomers. Thus, 20 mg of Prilosec (*i.e.*, omeprazole) is really 10 mg of the R-enantiomer and 10 mg of the S-enantiomer.

39. In humans, the S-enantiomer of omeprazole is more active than the R-enantiomer, in part due to its better metabolism.

40. Patent protection for omeprazole, the active ingredient in Prilosec, expired in all major markets by the end of 2000, but patent term extensions extended protection until April 2001 in the United States.

41. With the looming loss of patent protection, AstraZeneca faced the erosion of its number one selling drug. To put this in perspective, Prilosec sales of \$5.9 billion in 2000

comprised 39% of AstraZeneca's revenue, with sales of the Company's next best-selling drug comprising 8% of revenue.

B. AstraZeneca Was Keenly Aware That the Loss of Patent Protection Results in Lower Prices and Reduced Profits

42. At the time the Shark Fin Project was underway, AstraZeneca was keenly aware of the financial impact from the loss of brand-name protection.

43. For every year from 1995 through 2002, the pharmaceutical industry was the most profitable industry in the United States, although its profitability declined somewhat in 2002. In 2003, drug companies ranked as the third most profitable industry. Drug companies were more than three times as profitable as the median for all Fortune 500 companies in 2003 (14.3% compared to 4.6%).⁸

44. The most profitable drugs are brand name drugs. Brand name drugs typically sell at three or more times that of a generic drug. Once Prilosec lost patent protection, generic competition would erode Prilosec's price and market share.

C. The AstraZeneca Solution – “The New Purple Pill Nexium”

1. The Shark Fin Project

45. Faced with the catastrophic loss of sales from its flagship drug, AstraZeneca carefully plotted a new strategy. The plotting was done by members of the “Shark Fin Project,” a secret group of marketers, lawyers and scientists charged with developing a strategy for averting the Prilosec patent-expiration disaster. The name of the group derives from the dismal shape the sales chart would trace if AstraZeneca did nothing: an inverted V.

46. Eventually the centerpiece of that strategy became the marketing and promotion of the new drug Nexium. Nexium is simply the S-enantiomer of omeprazole, which was patented under the name esomeprazole. Thus, Nexium is simply Prilosec without the less active R-enantiomer. Nexium was viewed by several AstraZeneca executives as the poorest

⁸ Kaiser Family Foundation, *Trends as Indicators in the Charges*, Health Care Marketplace 2004 Update.

