

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

Monica Barba and Jonathan Reisman, on  
behalf of themselves and all others  
similarly situated,

Plaintiffs,

v.

SHIRE U.S., INC., a New Jersey  
Corporation, SHIRE, LLC, a Kentucky  
Limited Liability Company, and DOES 1  
through 100, inclusive,

Defendants.

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**No.**

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs, Monica Barba and Jonathan Reisman, individually and on behalf of all others similarly situated (the “Class”), bring this action against Defendants Shire LLC and Shire U.S., Inc. (collectively, “Shire” or “Defendants”), and allege, based on personal knowledge, investigation, and information and belief as to all other matters, as follows:

**I. NATURE OF ACTION**

1. This is a putative class action comprised of consumer indirect purchasers of Adderall XR (“AXR”), a popular prescription medication prescribed to treat attention deficit hyperactivity disorder (“ADHD”).

2. Defendants, Shire, are the manufacture of brand-name AXR. Defendants sell AXR under the brand name Adderall XR and also sell it as an “Authorized Generic” to generic companies to sell as a generic product.

3. Though other companies were able to bring an Authorized Generic to the market in 2009, Defendants engaged in a number of schemes meant to delay the entry of generic competition and then to restrict the supply of generic competition. Namely, Defendants filed

sham patent litigation, constructed anticompetitive reverse payment agreements with generic competitors, and even then proceeded to breach agreements to supply said competitors with materials to manufacture generic AXR, cutting off supply of cheaper-priced generic AXR to consumers.

4. Defendants' conduct constitutes an illegal restraint of trade and/or attempt at monopolization in violation of both federal and state antitrust statutes, which harmed consumers by restricting supply of generic AXR and forcing many to purchase the far more expensive brand-name medication sold by Defendants.

5. Plaintiffs therefore bring this action on behalf of themselves and a Florida Class of indirect purchasers of AXR, asserting that Defendants' anti-competitive behavior (in violation of the Sherman Act, the Florida Antitrust Act, and Florida's consumer protection laws) violates Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.*

## **II. PARTIES**

6. Plaintiff Monica Barba is, and at all times relevant hereto was, an individual residing in Miami-Dade County, Florida. During the Class Period, Plaintiff purchased AXR in Miami-Dade County for purposes other than resale.

7. Plaintiff Jonathan Reisman is, and at all times relevant hereto was, an individual residing in Orange County, Florida. During the Class Period, Plaintiff purchased AXR in Orange County for purposes other than resale.

8. Defendant Shire U.S., Inc. is a New Jersey corporation with its principal place of business and headquarters at 725 Chesterbrook Blvd., Wayne, Pennsylvania 19087. Throughout the Class Period, Shire U.S., Inc. marketed and sold AXR in Florida and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Adderall XR.

Further, upon information and belief, Shire U.S., Inc. maintains Shire's U.S. headquarters in Pennsylvania, and most of the wrongful conduct described herein emanated from Shire U.S., Inc.'s headquarters in Wayne, Pennsylvania. Throughout the Class Period, Shire U.S., Inc. marketed and sold AXR in Florida and elsewhere.

9. Defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire LLC is a successor entity to Shire Laboratories, Inc., a party to the anticompetitive reverse payment agreements at issue in this case. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including AXR. Throughout the Class Period, Shire LLC marketed and sold AXR in Florida and elsewhere.

10. The true names and capacities, whether individual, corporate, associated or otherwise of certain manufacturers, distributors, or their alter egos sued herein as DOES 1 through 100 inclusive are presently unknown to Plaintiffs who therefore sue these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend the Complaint to show their true names and capacities when the same have been ascertained. Plaintiffs are informed and believe and based thereon alleges that DOES 1 through 100 were authorized to do and did business in Miami-Dade County. Plaintiffs are further informed and believe and based thereon alleges that DOES 1 through 100 were or are, in some manner or way, responsible for and liable to Plaintiffs for the events, happenings, and damages hereinafter set forth below.

11. Plaintiffs are informed and believe and based thereon allege that at all times relevant herein each of the Defendants was the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego, or other representative of each of the remaining Defendants and was acting in such capacity in doing the things herein complained of and alleged.

### **III. JURISDICTION AND VENUE**

12. This Complaint is brought pursuant to Florida's Deceptive and Unfair Trade Practices Law, Fla. Stat. § 501.201, *et seq.* ("FDUTPA"), to seek redress for Defendants' unfair methods of competition, unconscionable acts or practices, and unfair conduct in violation of state law.

13. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum of \$5,000,000, exclusive of interest and costs, and is a class action in which members of the Class of plaintiffs are citizens of a State different from the Defendants.

14. Defendant has sufficient minimum contacts with Florida or otherwise intentionally avails itself of the consumer markets within Florida through the promotion, sale, marketing, and/or distribution of its products in Florida to render the exercise of jurisdiction by the Florida courts permissible under traditional notions of fair play and substantial justice.

15. Defendants transact business within this judicial district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district. Plaintiff Reisman and numerous Class Members reside in this district, purchased AXR and were thereby injured and subjected to irreparable harm in this district. Defendants received substantial compensation and profits from sales of AXR in this district. Thus, their liability arose in part in this district. Venue is therefore appropriate under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

### **IV. FACTUAL ALLEGATIONS**

#### **A. Adderall XR, Shire, and Generic Competition**

16. AXR is a once-a-day psychostimulant drug of the pherethylamine and amphetamine chemical classes indicated for treatment of attention deficit hyperactivity disorder

(ADHD).

17. In 1996, Shire released Adderall in an instant release formulation. It quickly became popular as an alternative to methylphenidate (sold under the brand name Ritalin) for treatment of ADHD. Studies indicate that Adderall is slightly more potent and has a longer period of efficacy than Ritalin, especially at lower doses.

18. In 2001, Shire introduced AXR, which added the additional convenience of once-a-day dosing.

19. AXR quickly became a major source of revenue and the flagship product for Shire. A small company founded in 1986, AXR transformed Shire into a major pharmaceutical company. In the decade following AXR's release, Shire's net sales topped \$6 billion. AXR was a major source of Shire's sales, in 2008 alone accounting for over \$1 billion in sales and nearly half of Shire's overall revenues.

20. Other drug companies sought entry into the AXR markets.

21. In November 2002, Barr Pharmaceuticals (which was acquired by Teva Pharmaceuticals USA, Inc. and will subsequently be referred to as "Teva") filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to manufacture and sell a generic formulation of AXR it had developed.

22. In September 2003, Impax Laboratories, Inc. ("Impax") filed an ANDA seeking to manufacture and sell its generic version of AXR.

**B. Shire's Sham Patent Litigation**

23. In February 2003, Shire filed a patent suit against Teva, alleging infringement of its '819 patent ("*Teva I*"). Shire filed a subsequent case against Teva in September 2003, alleging infringement of its '300 patent ("*Teva II*"). Both cases were filed in the Southern

District of New York.

24. Shire filed another patent suit against Impax in December 2003, alleging infringement of its '819 and '300 patents for 30 mg dosage ("*Impax I*"). Shire filed a subsequent case against Impax in January 2005, relating to additional dosage forms under the '819 and '300 patents ("*Impax II*"). Both cases were filed in the District of Delaware.

25. Shire's litigation conduct further underscored its bad faith use of the '819 and '300 patent litigation to extend its monopoly. For example, the Court in *Impax I* issued its Markman Order affecting claim construction of the '819 and '300 patents in February 2005. Sensing defeat in light of the Court's order, Shire sought reconsideration, a motion that Impax correctly described in pleadings as yet another attempt to delay generic entry into the market. The motion for reconsideration was denied.

26. Meanwhile, in a further efforts to undermine the Court's ability in *Impax I* to resolve the patent disputes, in March 2005 (a month after and undoubtedly in response to the unfavorable ruling) Shire claimed that discovery in the Teva litigation uncovered supposed errors in both the '819 and '300 patents, and Shire requested a reissuance of the '819 and '300 patents pursuant to 35 U.S.C. §251.

27. Yet when filing for re-issuance, Shire did not change any of the 42 claims asserted in those patents, but merely added additional claims.

28. The result of the purported "curing" of errors however was to greatly delay and hamper the Court's ability to resolve the case in favor of the generic manufacturers on summary judgment. Put plainly, Shire's '819 and '300 infringement claims were obvious sham claims filed merely to illegally extent its AXR monopoly.

29. In October 2005, Shire filed another patent suit, this time against both Teva and

Impax and alleging infringement of its '768 patent ("*Teva/Impax I*"). This case was filed in the Southern District of New York.

30. Shire's '768 patent was not even listed in the FDA's Orange Book, so there was no question that there was no basis for a patent suit by Shire. Under the Hatch-Waxman Act, a generic manufacturer has only infringed a patent if it is listed in the Orange Book; otherwise, generic manufacturers have a safe harbor in their preparation activities and there is no infringement until the generic manufacturer actually markets its product.

31. Further, the release-mechanism technology covered by the '768 patent, upon information and belief, was not even employed by Shire in the AXR product. Since the release mechanism covered by the '768 patent constituted a major change from those employed in AXR, it would not have even been possible (absent a bioequivalent test) for a product containing the '768 technology to be deemed bioequivalent to AXR. Both in procedure and in substance, the '768 patent suit was a sham meant to illegally extend Shire's AXR monopoly.

32. In the midst of its sham patent litigation, Shire's CEO Matt Emmens, in a remarkable moment of candor, described in a November 2005 interview his "tactics" for thwarting generic competition for AXR:

The US is also where the lawyers are, and Mr Emmens has had to spend a lot of time with them as Shire tries to defend its patents on Adderall, which most analysts forecast will face copycat competition after a courtroom showdown beginning in January. If a copycat version is allowed on the market, Adderall prices will certainly collapse. US parents, insurers and healthcare authorities might very much like that. Mr Emmens' task is to delay that until Shire's new products have established themselves.

Pharmaceuticals companies expend a great deal of brainpower on tactics for maintaining their monopoly positions, and Shire is trying every tactic in the book. It is pretty pleased with itself to date. It has filed extra patents on the way Adderall is made and is suing the generic drug makers for infringement of that and other patents. And it is asking regulators to insist that the generics firms

conduct human trials before being allowed to launch. This last tactic is “pretty elegant”, Mr Emmens says with a smile.

He has experience of this sort of battle, having worked in the joint venture between Merck of the US and Astra of Sweden which developed Prilosec, an ulcer drug which became the world's best-selling medicine. AstraZeneca managed to tie up the manufacturers of generic Prilosec in the courts for nearly two years after the core patents expired, thanks to a plan put in place many years before.

Stephen Foley, *Matt Emmens: Shire Pharmaceuticals chief focuses his attention on drugs deficit*, The Independent, Nov. 12, 2005.

33. In March 2006, Shire filed a patent case against Teva (who had now merged with Barr), alleging (again) infringement of its ‘819 and ‘300 patents (“*Teva III*”). This time, Shire filed in the Eastern District of Pennsylvania.

34. By filing suits alleging patent infringement, Shire was able to avail itself of various FDA regulations resulting in a 30-month automatic stay of FDA’s approval of the Teva and Impax ANDAs.

35. Upon information and belief, Shire’s patent litigation was a sham, asserting a patent that is invalid, void or otherwise unenforceable, and Shire used the patent litigation to extend the time during which it maintained a monopoly knowing that its monopoly was in jeopardy.

36. Shire’s motivation is obvious. Absent its sham litigation and dilatory litigation tactics, the patent litigation may have been resolved in favor of Teva or Impax before the conclusion of the 30-month stay, or the generic manufacturers might proceed to take the drug to market at conclusion of the stay “at risk” even while the patent lawsuits were pending. Of course, the availability of a much cheaper generic would have profound implications for Shire’s bottom line, likely causing it to lose ninety (90) percent of the market share for its blockbuster drug.

**C. Shire's Reverse Payment Agreements with Teva and Impax**

37. In 2006, Shire settled the patent litigation with Teva and with Impax. As part of the voluntary settlements, Shire made various payments to both Teva and Impax and the generic manufacturers agreed not to launch any generic AXR products until April (Teva) and October (Impax) of 2009. Thus, Shire was able to extend its monopoly for three more years.

38. In addition, Shire agreed to provide Teva and Impax with patent licenses so that they could legally sell Shire's formulation of AXR as an Authorized Generic in 2009, in the event the FDA had not yet approved Teva's and Impax's ANDA's for their own generic AXR. Shire would receive a royalty payment based on sales of its authorized generic AXR sold by Teva and/or Impax. Thus Shire retained complete control over the supply of AXR profiting from sales of the Brand and Authorized Generic product.

39. Further, the agreement contained a requirement contract component, in that Shire agreed to meet Teva's and Impax's supply requirement and provide AXR directly to the two generic companies. Because the FDA had not yet approved the Teva and Impax ANDAs in 2009, they would sell AXR manufactured by Shire as Authorized Generics.

40. The only difference between brand-name and generic AXR would be the trade dress and the price of each product. Shire continued to sell the brand product at a substantially higher price than the Authorized Generic. This further underscores the anticompetitive reasons that Shire was able to maintain such a large market share even though their product was much more expensive yet identical to that marketed by Teva and Impax.

41. Upon information and belief, the three-year extension of Shire's monopoly imposed a substantial cost on consumers and conferred a benefit to Shire. Through the settlement agreements, Shire provided consideration to Teva and Impax in exchange for their

delay into the market.

42. Other generic manufacturers followed Teva and Impax by filing ANDAs for generic AXR, and Shire treated them in the same manner as it did Teva and Impax, by filing sham patent infringement litigation and then reaching settlements prior to any ruling on the validity of Shire's patents.

**D. Shire's Intentional Breach of Supply Agreements**

43. Even after enjoying an extended monopoly over the market, on information and belief, Shire thereafter willfully breached its agreements with Teva and Impax by limiting the supply of the AXR product, such that Teva and Impax were unable to meet demand for the Authorized Generic.

44. Shire refused to supply AXR to Teva in violation of the Shire-Teva agreement. Upon information and belief:

a. Teva introduced its generic AXR product in April 1, 2009 at prices below those charged for brand name AXR, and quickly acquired a majority (approximately sixty percent) of the AXR market.

b. As required by their agreement with Shire, Teva on or around July 1, 2009 sent Shire a 12-month forecast of the predicted supply of AXR Teva would need. Along with that forecast was a purchase order (binding on Shire) for the months of October, November, and December 2009.

c. Shire, however, refused to honor the binding purchase order, and on or around August 28, 2009 notified Teva that it would not deliver the amount requested in the purchase order and would be delivering instead a much lower amount.

d. Then, on or around October 2, 2009, Shire notified Teva that it would not

even be providing the much-lower amounts of AXR it had promised in August. Meanwhile, Shire continued to provide the market with AXR to be sold under its brand-name (and more expensive) label. In short, through its anti-competitive behavior, Shire forced consumers to purchase an identical product for a much higher price.

e. A few days later, on or around October 5, 2009, Shire employee Jeff Cooperrider told Teva employee Jeff Keyser that the reason behind Shire's failure to deliver the product to Teva was Shire's management's decision to keep the product for itself.

f. By failing to deliver the amount of AXR purchased in the July 2009 purchase order, Shire breached its agreement with Teva. This breach continued via Shire's practice of restricting the supply from October 2009 on with the purpose and effect of hindering Teva's ability and incentive to compete in the AXR market.

45. Shire also refused to supply AXR to Impax in violation of the Shire-Impax agreement. Upon information and belief:

a. Impax, whose AXR product was scheduled to debut on or around October 1, 2009, notified Shire in the months leading up to October of its intent to rely upon Shire to supply Impax's AXR product. On information and belief, Impax timely submitted its purchase order for the amount needed for the initial launch, and continued to timely submit purchase orders thereafter based upon its forecasts.

b. Starting in 2009, Shire failed to timely fill Impax's purchase orders. Upon information and belief, the problem intensified in 2010 when Shire not only failed to timely deliver product, but in many instances delivered less than what was ordered or delivered none at all. These repeated breaches of the agreement had the purpose and effect of hindering Impax's ability and incentive to compete in the AXR market.

c. According to court documents filed by Impax, Shire's behavior had devastating effects. As noted by the company:

Impax consistently lacked sufficient supply of generic AXR. As a result of this lack of supply, Impax was unable to fill many of its customers' purchase orders. Impax also was forced to ration product to its customers or delay delivering product to its customers as a result of Shire's failure to supply. Impax's customers would have ordered more generic AXR if it were available. On several occasions, customers approached Impax seeking to purchase more generic AXR, but Impax had to turn them away before any purchase orders were placed because it had no stock available.

.....

As a result of Shire's failure to supply Impax with generic AXR, Impax lost sales to existing customers, lost the opportunity to execute more favorable contracts with its customers, and was unable to solicit additional customers.

....

By starving Impax of supply, Shire ensured that Impax could not compete. Without sufficient supply Impax was unable to fill the orders of its customers, unable to provide those customers with additional product they wanted to buy, and unable to solicit new customers. Shire, on the other hand, has been able to line its pockets with tens of millions of dollars every month from sales of branded AXR by refusing to fill Impax's orders and keeping supply for itself. Indeed, as a result of Shire's actions, more than two years after generic entry, Shire's branded AXR accounts for approximately 40% of the total AXR market.

46. Upon information and belief, had Shire met its obligation to supply AXR to Teva and Impax, the generic manufacturers would have captured roughly ninety (90) percent of the market. But in or around late 2009, Shire began improperly limiting the supply of AXR to the generic manufacturers, such that they were only able to capture little more than half of the market.

47. Thus, even though consumers faced much more expensive co-pays for brand name medication, upon information and belief Shire was able to maintain a forty (40) percent market share, which is unheard of following the availability of a cheaper, generic version of the

drug.

48. By breaching the agreement, and ensuring that supply of generic AXR did not meet demand, Shire forced tens if not hundreds of thousands of consumers to expend significantly more money and purchase Shire's branded product.

49. Further, upon information and belief, with the supply of generic alternatives dwindling, Shire raised the price of brand name AXR while simultaneously eliminating discounts and rebates. Thus not only was Shire able to maintain its monopoly prices, but through its anticompetitive acts, it was able to *raise* them.

**E. The Supply Shortage and Monopoly Created by Defendants' Conduct**

50. Shire can offer no justification for its conduct, and the DEA has rejected the notion that the AXR shortage was due to the DEA's failure to set a manufacturing quota high enough to meet demand.

51. Upon information and belief, the AXR shortage was the result of Shire's management who created the shortage in order to increase the brand name market for the drug, as Shire controlled the supply for AXR—both brand name and generic.

52. As evidence of Shire's anticompetitive effect, Shire in late 2010 was actually able to *raise* the price of AXR. Even after raising the prices and increasing its own revenue, Shire still refused to reallocate the supply of AXR to Teva and Impax. During this time Shire actually increased its self-allocation of AXR from forty (40) percent of the total AXR allocated to fifty (50) percent. In this sense, Shire's breach of its supply agreements allowed it to charge artificially inflated prices. Even while Shire raised its prices, it was able to increase its market share.

53. As a result, Shire reported in the third quarter of 2010 that AXR sales had

increased forty-one (41) percent to \$99.7 million (for the quarter). The sales numbers continued to climb, and in the first two quarters of 2011 Shire reported AXR sales of \$111 million and \$146.9 million.

**F. Effect on Interstate Commerce, Market Power, and Competition**

54. At all relevant times, Defendants manufactured, sold, and shipped AXR across state lines including into Florida.

55. At all relevant times, in connection with its sales of AXR, monies, contracts, bills, and business communications were transmitted continuously and uninterruptedly across state lines, including into Florida.

56. At all relevant times, various devices were employed to commit the illegal acts described herein, including U.S. mail, interstate travel, interstate telephone communications, and interstate commerce. Defendants' complained-of activities occurred within the stream of, and have substantially affected, interstate commerce.

57. In this case, as alleged herein, there is direct proof of Defendants' monopoly power over the price of AXR. This direct proof includes, but is not limited to: (a) Shire's exclusion of competition from the market by way of its agreements with Teva and Impax; (b) Shire's exclusion of competition from the market by way of Shire's refusal to honor the supply agreements with Teva and Impax; (c) Shire's unprecedented market share for AXR after generic drugs are introduced into the marketplace; (d) Shire's status as the only supplier of AXR; (e) price data demonstrating Shire's ability to raise its prices without losing sufficient sales to render the price increases unprofitable; and/or (f) the lack of non-AXR drug products that can be reasonably substituted for AXR.

58. The relevant product market is Adderall XR and its generic equivalents, in all

forms and dosage strengths.

59. The relevant geographic market is nationwide. Through the illegal conduct described herein, Defendants were able to charge artificially high prices without losing substantial sales, and thus, by definition, maintained monopoly power over AXR products sold in the United States and Florida.

60. Through the illegal conduct described herein, Defendants intentionally, purposefully, and successfully suppressed competition. Defendants' exclusionary conduct suppressed the sale of AXR in the United States and Florida, and unlawfully enabled Defendants to sell AXR Product at artificially inflated prices.

61. If Teva and Impax had effectively competed with Defendants, they would have captured a much greater share of the overall AXR market than Defendants, and Plaintiffs and Class Members would have substituted more lower-priced AXR for the higher-priced brand name AXR<sup>1</sup>.

62. During the relevant time period, Plaintiffs and Class Members purchased AXR indirectly from Defendants. As a result of Defendants' anticompetitive and illegal conduct, Plaintiffs and Class Members had to pay more money in the form of higher prices or co-pays for "brand name" medication even though it was precisely the same as the generic medication. This is because Plaintiffs and Class Members were deprived of the ability to purchase lower-priced generic AXR or Authorized Generic Adderall at competitive market prices.

63. Thus Plaintiffs and the Class Members, as a result of Defendants' illegal conduct, have suffered monetary losses and damages.

**G. Factual Allegations as to Named Plaintiffs**

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<sup>1</sup> "The first-time introduction of a generic drug shows large welfare gains due to expansion of the market to price sensitive consumers." See F. Bokhari & G. Fournier, "Entry in the ADHD Drugs Market: Welfare Impact of Generics and Me-Toos," at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1401546](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1401546).

64. Monica Barba, a resident of Miami-Dade County, was prescribed AXR on or around February 2009, and continues to take it periodically through the present.

65. Ms. Barba had an insurance policy through Aetna. Under the policy, Ms. Barba had to spend significantly more for brand name medication where there was an FDA-approved generic. The co-pay for brand name medications, the amount Ms. Barba had to spend, was more for brand-name drugs than for generic drugs.

66. Plaintiff Barba was an indirect purchaser of AXR.

67. On numerous occasions during the Class Period, Plaintiff Barba was unable to procure generic AXR due to a lack of generic supply, and had to expend considerably more personal funds to purchase the brand name AXR.

68. Jonathan Reisman, a resident of Orange County, was prescribed AXR on or around late 2005 / early 2006. He continued to take AXR through 2009.

69. Mr. Reisman had an insurance policy through Aetna. Under the policy, Mr. Reisman had to spend significantly more for brand name medication where there was an FDA-approved generic. The co-pay for brand name medications, the amount Mr. Reisman had to spend, was more for brand-name drugs than for generic drugs.

70. Plaintiff Reisman was an indirect purchaser of AXR.

71. On numerous occasions during the Class Period, Plaintiff Reisman was unable to procure generic AXR due to a lack of generic supply, and had to expend considerably more personal funds to purchase the brand name AXR.

## **V. CLASS REPRESENTATION ALLEGATIONS**

**A. Class Definition**

72. Plaintiffs bring this action pursuant to Federal Rules of Civil Procedure 23(b)(2) and (b)(3) on behalf of themselves and on behalf of the Class defined below. The proposed Class consists of:

**All persons residing in the State of Florida who purchased brand name AXR for personal use and not for resale.**

73. Excluded from the Class are governmental entities, Defendants, any entity in which Defendants have a controlling interest, and Defendants' officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries and assigns. Also excluded from the Class are any judge, justice or judicial officer presiding over this matter.

74. Said definition may be further defined or amended by additional pleadings, evidentiary hearings, a class certification hearing, and orders of this Court.

**B. Fed. R. Civ. P. 23(a) Factors**

75. **Numerosity.** The members of the Class are so numerous that separate joinder of each member is impracticable. Plaintiffs do not know the exact number of members in the Class, but based upon information and belief, Plaintiffs reasonably believe that Class Members number at a minimum in the thousands.

76. **Commonality.** The claims of Plaintiffs raise questions of law or fact common to the questions of law or fact raised by the claims of each member of the Class. Plaintiffs' claims arise from the same practice or course of conduct that gives rise to the claims of the Class members. The questions of law and fact common to Plaintiffs and the Class predominate over questions affecting only individual Class members, and include, but are not limited to, the following:

a. Whether Defendants' reverse payment agreements with generic

manufacturers constitute the illegal restraint of trade in violation of Section 1 of the Sherman Act and/or Florida Antitrust Act;

- b. Whether Defendants' violations of Section 1 of the Sherman Act constitute violations of FDUTPA;
- c. Whether Shire's patent infringement lawsuits filed against Teva, Impax and others were filed with the improper purpose of preventing entry of competing generic products into the market, in violation of Section 2 of the Sherman Act and/or Florida's Antitrust Act;
- d. Whether Defendants' reverse payment agreements with generic manufacturers constitute monopolization and/or attempted monopolization in violation of Section 2 of the Sherman Act and/or Florida's Antitrust Act;
- e. Whether Defendants' intentional breach of the supply agreements constitute monopolization and/or attempted monopolization in violation of Section 2 of the Sherman Act and/or Florida's Antitrust Act;
- f. Whether Defendants' violations of Section 2 of the Sherman Act constitute violations of FDUTPA;
- g. Whether Defendants' conduct violated the Florida Antitrust Act;
- h. Whether Defendants' violations of the Florida Antitrust Act constitute violations of FDUTPA;
- i. Whether a relevant market needs to be defined in this case in light of the existence of direct evidence of Defendants' power to exclude generic competition and set supracompetitive prices for AXR Product;
- j. If a relevant market needs to be defined, the definition of the relevant

market for analyzing Defendants' monopoly power, and whether Defendants had monopoly power in the relevant market;

k. Whether, independent of whether Defendants' conduct violated the Sherman Act or Florida's Antitrust Act, Defendants' conduct constitutes unfair and/or fraudulent practices in violation of FDUTPA; and/or

l. Whether Plaintiffs and the Class have been injured as a result of Defendants' anti-competitive conduct, and the amount of damages.

77. **Typicality.** The claims of Plaintiffs are typical of the claims of each member of the Class. Defendants engaged in a standardized course of conduct affecting the Class Members, and Plaintiffs' alleged injuries arise out of that conduct. All Class Members, including Plaintiffs, have the same or similar injury to their property (i.e. paying higher prices for AXR) as a result of Defendants' anti-competitive conduct.

78. **Adequacy.** Plaintiffs can fairly and adequately protect and represent the interests of each member of the Class. Plaintiffs fit within the class definition and their interests do not conflict with the interest of the members of the Class they seek to represent. Plaintiffs are represented by experienced and able attorneys. The undersigned Class Counsel have litigated numerous class actions and complex cases and intend to prosecute this action vigorously for the benefit of the entire Class. Plaintiffs and Class Counsel can and will fairly and adequately protect the interests of all members of the Class.

**C. Fed. R. Civ. P. 23(b)(2) Factors**

79. Defendants acted on grounds generally applicable to the entire Class, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Class as a whole. The prosecution of separate actions by individual Class Members would

create the risk of inconsistent or varying adjudications with respect to individual members of the Class that would establish incompatible standards of conduct for Defendants.

80. Injunctive relief is necessary to prevent further anti-competitive conduct by Defendants. Money damages alone will not afford adequate and complete relief, and injunctive relief is necessary to restrain Defendants from continuing to engage in conduct which restrains, suppresses, and/or eliminates competition in the United States and Florida for the sale of AXR.

**D. Fed. R. Civ. P. 23(b)(3) Factors**

81. **Common issues predominate:** As set forth in detail above, common issues of fact and law predominate because all of Plaintiffs' claims are based on identical anti-competitive conduct.

82. **Superiority:** Additionally, a class action is superior to other available methods for fair and efficient adjudication of the controversy. The damages sought by each Class Member are such that individual prosecution would prove burdensome and expensive given the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for the members of the Class to effectively redress the wrongs done to them on an individual basis. Even if the members of the Class themselves could afford such individual litigation, it would be an unnecessary burden on the courts.

83. The trial and litigation of Plaintiffs' claims are manageable. Individualized litigation presents a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and to the court system presented by the legal and factual issues raised by Defendants' conduct. By contrast, the class action device will result in substantial benefits to the litigants and the Court by allowing the Court to resolve numerous individual claims based upon a single set of proof in just one case.

84. Further, Defendants have acted on grounds generally applicable to the Class, thereby making final injunctive relief with respect to the Class as a whole appropriate. Moreover, on information and belief, Plaintiffs allege that the conduct complained of herein is substantially likely to continue in the future if an injunction is not entered.

85. **Notice to the Class:** Notice to the Class may be made by publication.

## **VI. CAUSES OF ACTION**

### **A. First Cause of Action: Violations of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (premised on Section 1 of the Sherman Act)**

86. Plaintiffs repeat and reallege the allegations set forth above, and incorporate the same as if set forth herein at length.

87. Plaintiffs and the Class are “consumers” within the meaning of Fla. Stat. § 501.203(7).

88. Defendants’ conduct alleged herein relating to the sale of AXR constitutes “trade or commerce” within the meaning of Fla. Stat. § 501.203(8).

89. FDUTPA declares “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce” to be unlawful. Fla. Stat. § 501.204(1).

90. Violations of Section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) constitute unfair, unconscionable, and/or deceptive acts or practices in violation of FDUTPA.

91. By violating Section 1 of the Sherman Act, 15 U.S.C. § 1, Defendants have violated the Federal Trade Commission Act and engaged in unfair competition and/or unconscionable/unfair acts or practices in violation of FDUTPA.

92. Further, by violating Section 1 of the Sherman Act, Defendants violated a statute proscribing an unfair method of competition.

93. Further, by violating Section 1 of the Sherman Act, Defendants have engaged in an unfair practice. Defendants' violations of Section 1 of the Sherman Act offend established public policy, and are immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

94. Defendants violated Section 1 of the Sherman Act by engaging in the unlawful, anti-competitive conduct set forth herein. Defendants have unreasonably restrained trade and commerce in the relevant product market in violation of Section 1 of the Sherman Act. But for the anti-competitive practices Defendants would not have been able to maintain their monopoly power over the price of AXR in the relevant market.

95. Defendant acted in concert with Teva, Impax, and other generic manufacturers in furtherance of the illegal restraint of trade complained of herein.

96. Defendant's reverse payment settlements with Teva and Impax constitute *per se* unreasonable restraints of trade. Alternatively, the reverse payment settlements had an unreasonable adverse effect on competition in the properly defined relevant market.

97. Shire's agreements with Teva and Impax were comprised of payments from Shire to Teva and Impax, who in turn agreed to delay entry into the market. As such, this is an unreasonable restraint of trade. The agreements were for no purpose other than delay the generic manufacturers' entry into the drug market and offered no pro-competitive benefits.

98. Competition, including price competition at the consumer level for AXR (through the emergence of generic alternatives) will continue to be restrained, suppressed or eliminated as a result of Defendants' anti-competitive conduct described herein. The actual adverse effects of

these agreements include, but are not limited to:

- a. Shire's control of the AXR and Authorized Generic market;
- b. The delayed entry of generic competition into the AXR market;
- c. A restraint on output of generic AXR; and/or
- d. Higher prices for brand name AXR (due to shortage of generic competition).

99. The agreements were further *per se* anticompetitive for these reasons.

100. Here, the relevant market is AXR and its generic equivalents sold nationwide.

101. Competitors, actual and potential, have been, and will continue to be, restrained from vigorously competing with one another for selling AXR as a result of Defendant's anti-competitive conduct.

102. Indirect purchasers (including Plaintiffs and members of the putative Class), have been injured in their business and property because they have been deprived of choice, and have paid inflated prices for AXR (or paid higher co-pays for brand name medications), which they otherwise would not have had to pay in the absence of Defendants' anti-competitive conduct. Plaintiffs' and the Class's injuries flow from Defendants' unlawful conduct.

103. Because of Defendants' violations of Section 1 of the Sherman Act (and hence FDUTPA), consumers (including Plaintiffs and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product. These are the types of injuries the Sherman Act seeks to prevent.

104. As a direct and proximate result of Defendants' violations of Section 1 of the Sherman Act (and hence FDUTPA), Plaintiffs and the Class have suffered a loss of money and suffered actual damages.

105. There is no federal or state law which affirmatively authorizes Defendants to engage in the conduct alleged throughout this Complaint.

106. In addition to actual damages, Plaintiffs and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105 and 501.211.

**B. Second Cause of Action: Violations of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (premised on Section 2 of the Sherman Act)**

107. Plaintiffs repeat and reallege the allegations set forth above, and incorporate the same as if set forth herein at length.

108. By violating Section 2 of the Sherman Act, 15 U.S.C. § 2, Defendants have violated the Federal Trade Commission Act and engaged in unfair competition and/or an unconscionable/unfair act or practice in violation of FDUTPA.

109. Further, by violating Section 2 of the Sherman Act, Defendants violated a statute proscribing an unfair method of competition.

110. Further, by violating Section 2 of the Sherman Act, Defendants have engaged in an unfair practice. Defendants' violations of Section 2 of the Sherman Act offend established public policy, and are immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

111. Defendants violated Section 2 of the Sherman Act. Defendants attempted to and successfully monopolized power over the price of AXR, and over the relevant market—AXR and its generic equivalents—nationwide and in the State of Florida. But for Defendants' exclusionary, anti-competitive practices, as set forth at length above, Defendant would not have been able to maintain its monopoly power over the price of AXR in the relevant market.

112. Defendant violated Section 2 of the Sherman Act in three ways, and taken

together further illustrate a successful attempt to exert an illegal monopoly of the price of ACT and over the relevant market. Defendants (1) engaged in sham patent litigation; (2) entered into reverse payment agreements; and (3) intentionally breached its supply agreements with Teva and Impax. All of these actions were done to restrict generic AXR output and furthered Defendants' monopolization of the AXR market, excluding generic manufacturers from participating.

113. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by excluding and impeding competition from the market for AXR. The goal, purpose and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic AXR competitors, who would have sold generic versions nationwide and in Florida at prices significantly below Defendants' prices for AXR, and therefore would have taken most of Defendants' market share. Such generic competition would have effectively caused the average market price of AXR to decline dramatically.

114. Defendants have willfully acquired and/or maintained their monopoly power over the market for the sale of AXR, not through superior skill and/or product, business acumen, or enterprise, but rather through the foregoing anti-competitive and exclusionary conduct. Defendants' conduct in engaging in the sham patent litigation and/or intentionally breaching its supply agreements ran afoul of Section 2 of the Sherman Act.

115. There is no appropriate or legitimate business justification for the actions and conduct which have facilitated Defendants' monopolization of the United States market for the sale of AXR.

116. Direct purchasers, and indirectly their consumers (including Plaintiffs and members of the putative Class), have been injured in their business and property because they have been deprived of choice, and have paid inflated prices for AXR, which they otherwise

would not have had to pay in the absence of Defendants' anti-competitive conduct. Plaintiffs' and the Class's injuries flow from Defendants' unlawful conduct.

117. Because of Defendants' violations of Section 2 of the Sherman Act (and hence FDUTPA), consumers (including Plaintiffs and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product. These are the types of injuries the Sherman Act seeks to prevent.

118. As a direct and proximate result of Defendants' violations of Section 2 of the Sherman Act (and hence FDUTPA), Plaintiffs and the Class have suffered a loss of money and suffered actual damages.

119. In addition to actual damages, Plaintiffs and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105 and 501.211.

**C. Third Cause of Action: Violations of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (premised on Fla. Antitrust Act)**

120. Plaintiffs repeat and reallege the allegations set forth above, and incorporate the same as if set forth herein at length.

121. By violating the Florida Antitrust Act, Fla Stat. § 542.15 *et seq.* ("FAA"), Defendants have engaged in unfair competition and/or an unconscionable/unfair act or practice in violation of FDUTPA.

122. Further, by violating the Florida Antitrust Act, Defendants violated a statute proscribing an unfair method of competition.

123. Further, by violating the Florida Antitrust Act, Defendants have engaged in an unfair practice. Defendants' violations of the Florida Antitrust Act offend established public policy, and are immoral, unethical, oppressive, unscrupulous, and substantially injurious to

consumers.

124. Defendants violated the FAA. The FAA was adopted to foster effective competition and complement the body of federal law (including the Sherman Act) prohibiting restraints of trade or commerce. Under the FAA, every contract, combination, or conspiracy in restraining Florida trade or commerce is unlawful. It is further unlawful to monopolize or attempt to monopolize any part of Florida trade or commerce.

125. Defendants are “persons” within the meaning of Fla. Stat. § 542.17(3).

126. AXR is a “commodity” within the meaning of Fla. Stat. § 542.17(1), and therefore Defendants’ business marketing, selling, and/or distributing AXR is “trade or commerce” within the meaning of Fla. Stat. § 542.17(4).

127. The actions described herein, including but not limited to (1) the sham patent litigation, (2) the reverse payment agreements, and/or (3) Defendants’ intentional breach of its supply agreements with Teva and Impax to capture more market share for itself, constitute illegal restraints of trade, monopolization of trade and/or an attempt to monopolize trade or commerce in Florida and the United States.

128. As a result of the actions described herein, Defendants attempted to acquire a monopoly in Florida and the United States, possessed a monopoly power in Florida and the United States which affected the price of AXR, and acquired that monopoly power in an exclusionary manner.

129. Through the actions described herein, Defendants—throughout the United States including Florida—possessed the ability to affect price and/or output. The reverse payment agreements and/or Defendants’ intentional breach of the supply agreements were intended to and did affect the price or supply of AXR in the market.

130. Defendants' wrongful conduct had a substantial anticompetitive effect on commerce within the State of Florida and nationwide.

131. The anticompetitive effect of Defendants' actions aside, Defendants' conduct in misallocating the supply of AXR and price-fixing are *per se* violations of the FAA.

132. As a direct and proximate result of Defendants' violations of the Florida Antitrust Act (and hence FDUTPA), Plaintiffs and the Class have suffered a loss of money and suffered actual damages.

133. In addition to actual damages, Plaintiffs and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105 and 501.211.

**D. Fourth Cause of Action: Violations of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (unfair practices – not premised on violations of Sherman Act or Florida Antitrust Act)**

134. Plaintiffs repeat and reallege the allegations set forth above, and incorporate the same as if set forth herein at length.

135. Independent of whether Defendants' conduct violated the Sherman Act or Florida Antitrust Act, Defendants' conduct, as described throughout the complaint, are unfair practices in violation of FDUTPA.

136. First, by utilizing sham patent litigation to delay the entry into the market of generic version of AXR, Defendant engaged in an unfair practice which caused Plaintiffs and the Class to pay more for AXR than they would have but for this wrongful conduct.

137. Second, by contriving with the generic manufacturers to enter into reverse payment agreements, Defendants delay the entry into the market of generic version of AXR, and thus engaged in an unfair practice which caused Plaintiffs and the Class to pay more for AXR

than they would have but for this wrongful conduct.

138. Third, by intentionally breaching the supply agreements with the generic manufacturers, Defendants further artificially controlled the supply and cost of AXR, causing Plaintiffs and the Class to pay more for AXR than they would have but for this wrongful conduct.

139. Defendants' unfair practices, as described here, offend established public policy, and are immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers. Defendants forced users of its prescription medication, who had no reasonable alternatives, to pay higher prices well into the period in which generic alternatives to AXR should have been available. Defendants were motivated solely by profit at the expense of Plaintiffs and the Class.

140. As a direct and proximate result of Defendants' unfair practices (which violate FDUTPA), Plaintiffs and the Class have suffered a loss of money and suffered actual damages.

141. In addition to actual damages, Plaintiffs and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105 and 501.211.

**E. Fifth Cause of Action: Violations of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (deceptive acts – not premised on violations of Sherman Act or Florida Antitrust Act)**

142. Plaintiffs repeat and reallege the allegations set forth above, and incorporate the same as if set forth herein at length.

143. Independent of whether Defendants' conduct violated the Sherman Act or Florida Antitrust Act, Defendants' conduct, as described throughout the complaint, are deceptive acts in violation of FDUTPA.

144. Plaintiffs bring this count on their own behalf and on behalf of all Class members.

145. Defendants sale of pharmaceuticals constitutes “[t]rade or commerce” under FDUPTA.

146. Plaintiffs and Class members are “consumers” under Fla. Stat. § 501.203 who purchased AXR for personal use, and not for resale.

147. Each Defendant is a “person” or “entity” as used in the FDUPTA.

148. Defendants engaged in deceptive conduct in violation of the Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* when they (1) initiated baseless sham patent litigation and/or (2) entered into supply agreements with the hidden intent to breach said agreements with the generic manufacturers, Teva and Impax, in order to artificially control the supply and cost of AXR in the marketplace. Defendants’ sham patent litigation and intentional breach of the agreements with Teva and Impax restricted generic AXR output and furthered Defendants’ monopolization of the AXR market.

149. Defendants further engaged in deceptive conduct when they falsely and publically claimed that they breached the supply agreements with Teva and Impax because the DEA failed to set a manufacturing quota high enough to meet demand.

150. The goal, purpose and/or effect of Defendants’ deceptive scheme was to prevent, delay, and/or minimize the success of the entry of generic AXR competitors, who would have sold generic versions nationwide and in Florida at prices significantly below Defendants’ prices for AXR.

151. As a direct and proximate result of Defendants’ deceptive conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of AXR, from July 1, 2009 to the present.

152. Plaintiffs and members of the Class have been injured in their business and

property by reason of Defendants' anticompetitive and deceptive acts alleged in this Count. The injury consists of paying higher prices for AXR prescription drugs than they would have paid in the absence of these violations. This injury is of the type Fla. Stat. § 501.201, *et seq.* was designed to prevent and directly results from Defendants' unlawful conduct.

153. In addition to actual damages, Plaintiffs and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. § 501.201, *et seq.*

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, on behalf of themselves and on behalf of the members of the Class defined herein, pray for judgment and relief on all Causes of Action as follows:

- A. An order certifying that the action may be maintained as a Class Action;
- B. The acts alleged herein be adjudged and decreed to be an unfair, deceptive and/or fraudulent business practices violating FDUTPA;
- C. That judgment be entered against Defendants, and each of them jointly and severally, for damages as a result of Defendants' FDUTPA violations;
- D. That judgment be entered against Defendants and in favor of Plaintiffs and the Class on the Plaintiffs' FDUTPA claim, for actual and consequential damages, equitable relief, including restitution and restitutionary disgorgement;
- E. An order enjoining Defendants from pursuing the policies, acts, and practices complained of herein;
- F. Actual damages;
- G. For pre-judgment interest from the date of filing this suit;
- H. Reasonable attorneys' fees;

I. Costs of this suit; and

J. Such other and further relief as the Court may deem necessary or appropriate.

**JURY TRIAL DEMANDED**

April 2, 2013

Respectfully submitted,

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