UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG COMPANY, INC., on behalf of itself and all others similarly situated, Plaintiff, v. SHIRE LLC, and SHIRE U.S., INC., Defendants.	12 CIV 3711 JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Louisiana Wholesale Drug Company, Inc., ("Louisiana Wholesale" or "Plaintiff") on behalf of itself and all others similarly situated, for its Class Action Complaint ("Complaint") against defendants Shire LLC, 9200 Brookfield Court, Florence, KY 41042-2969, and Shire U.S., Inc., 725 Chesterbrook Boulevard, Wayne, PA 19087 ("Shire U.S.") (collectively "Shire" or "Defendants") allege as follows based on: (a) personal knowledge; (b) the investigations of counsel, including various pleadings and memoranda in *Teva Pharm. U.S.A., Inc. v. Shire LLC*, United States District Court for the Southern District of New York, No. 09-cv-8860 (MGC), and *Impax Laboratories, Inc, v. Shire LLC, et al.*, United States District Court for the Southern District of New York, No. 1:10-cv-08386 (MGC), discussed herein; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiff on behalf of itself and a class of

direct purchasers against Shire, seeking treble damages and other relief because Shire unlawfully excluded, impeded and/or restrained generic competition for the specific mixture of amphetamine salts that is marketed and sold under the brand name Adderall XR (Adderall XR and its generic equivalents are collectively referred to herein as "AXR Product"). As alleged below, Shire devised an implemented a scheme involving various acts, including in particular and without limitation, improperly refusing to provide critical supplies of AXR Product to two of its generic competitors despite two separate voluntary agreements to do so, all for the anticompetitive purpose of impeding generic rivals so that Shire could sell its branded Adderall XR product at supracompetitive prices.

2. Since October 2001, Shire has manufactured and sold Adderall XR for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). When it launched Adderall XR, Shire was a little-known pharmaceutical company. Adderall XR quickly changed that, becoming a blockbuster brand-name drug that, according to Shire, "fueled Shire's rise as a leading specialty biopharmaceutical company." The result was that from October 2001 through September 2011, Shire realized net sales of over $6.5 billion. At its height, in 2008, Adderall XR's sales were $1.1 billion, accounting for 47% of Shire's overall revenues that year.

3. While Adderall XR had the potential to transform the company by generating hundreds of millions of dollars each year, the patents that protected Shire's monopoly were under early attack. In November 2002 (just one year after Adderall XR hit the market), Teva Pharmaceuticals USA, Inc. ("Teva")[1] filed an Abbreviated New Drug Application ("ANDA")

[1] A predecessor entity, Barr Pharmaceuticals ("Barr"), was in fact threatening entry at this time and was a party to the transactions discussed in paragraphs below. However, in December 2008, Barr was acquired by Teva and Barr's rights and obligations as they relate to this complaint were transferred to Teva. Therefore, for ease of reference, these entities are collectively referred to herein as "Teva."

seeking approval from the Food and Drug Administration ("FDA") to manufacture and sell a less-expensive generic version of Adderall XR. A year later, Impax Laboratories, Inc. ("Impax") also filed an ANDA seeking FDA permission to sell its own less-expensive, generic version of Adderall XR. In so doing, both Teva and Impax challenged Shire's patents for Adderall XR.

4. Shire sued Teva and Impax for patent infringement and in so doing was able to automatically stay FDA approval of Teva and Impax's ANDAs for up to 30 months based on various FDA laws and regulations. Nonetheless, Shire's monopoly was at risk because of the danger that: (a) a court might rule that Shire's patents were invalid or not infringed by Teva or Impax's proposed generic products; or (b) the possibility that after the 30 month stay expired Teva or Impax might launch their products "at risk" even while the patent lawsuits were pending. Either event could, and typically does, open the flood gates of generic competition, resulting in lower prices for purchasers and the branded-product manufacturer's dramatic loss in sales as customers shift to less-expensive generic version(s). As Shire would have known, generic competitors would charge substantially less for generic versions of Adderall XR, and thus once generic competition entered the market Shire would likely lose 90% or more of its Adderall XR sales.

5. Shire eliminated this immediate threat by voluntarily settling the patent suits with Impax and Teva in January 2006 and August 2006, respectively. The voluntary settlements ensured that Teva and Impax would not launch any generic AXR Products until April 1, 2009 and October 1, 2009, respectively, and thereby guaranteed that Shire would have its monopoly for an additional three years.

6. In exchange for the benefit of a 3-year guarantee on its monopoly, Shire

voluntarily agreed under the settlements to: (a) provide Teva and Impax with patent licenses so that they could start selling generic versions of Adderall XR in April 2009 and October 2009, respectively, without any liability; and (b) provide all of Teva and Impax's requirements for finished AXR Product, so that even if these generics did not have FDA final approval to make and sell their proposed products by 2009 they could still compete by selling the versions of the finished pills that Shire supplied. Thus, Shire voluntarily agreed that, in exchange for a 3-year guarantee on its monopoly, Shire would eliminate two competitive barriers for Teva and Impax (i.e., the patents and supply issues), thereby exposing its monopoly to guaranteed competition on a date certain. The expected result was that once Shire eliminated the competitive barriers, it would ultimately lose 90% or more of its monopoly-priced sales to its cheaper rivals.

7. Such agreements are not unusual in the pharmaceutical industry. Patent litigation is typical between brand-name companies and generic companies seeking to sell less-expensive versions of the brand drug prior to expiration of the applicable patent(s). In fact, such litigation is provided for and encouraged in the Hatch-Waxman Act. It is also not unusual for brand and generic companies to resolve their patent litigation by splitting the life of the applicable patent(s) based on their respective evaluations of the strengths and weaknesses of the patent case. Absent some sort of improper collusion between the brand and generic companies, such settlements typically constitute a win-win in that the brand company maintains its monopoly for a guaranteed period of time and the generics are given a guaranteed entry date that is prior to expiry of the patent(s). The expectation and experience in such situations (absent collusion) is that once generic entry occurs on the agreed upon date brand-generic competition will occur as normally experienced in the pharmaceutical industry: i.e., the generic product(s) will be sold at prices

lower than that of the brand, substantial market share will shift to the generic version(s) of the product, and purchasers will be able to buy as much or as little of the brand and generic versions of the product as desired.

8. In this case, Shire intentionally disrupted: (a) the competitive process envisioned in its agreements with Teva and Impax; and (b) the competitive process that normally takes place by and through such settlement agreements of Hatch-Waxman patent cases. After making voluntary promises for the express purpose of keeping Teva and Impax from competing for sales of AXR Product until 2009 – and after it received billions of dollars in sales because the deal preserved its monopoly for an extra 3 years – Shire willfully breached its contractual obligations by arbitrarily limiting Teva and Impax's supply of AXR Product. Specifically, rather than providing Teva and Impax with the amounts of finished AXR Product that the generics requested (which would have allowed these companies to capture 90% or more of Shire's sales of AXR Product), beginning in October 2009 Shire improperly limited supply of AXR Product so that Teva and Impax could collectively capture a maximum of 50 - 60% of the market. Without the supply needed to fill orders, Teva and Impax had neither the ability nor motivation to actively price compete against Shire (or each other) as they otherwise would have and as is customary in the pharmaceutical industry. The artificial supply shortfall of less-expensive, generic AXR Product that Shire created forced purchasers to buy Shire's higher priced branded Adderall XR, enabling Shire to retain for itself 40 - 50% of the AXR Product market even though it charged substantially more for a product that was identical to the products that Teva and Impax sold for far less. Because it was able to illegally maintain Adderall XR sales at monopolistic, supracompetitive prices, Shire has earned hundreds of millions of dollars at purchasers' expense

that Shire would not have earned in a competitive market.

9. As a result of the willful breach of the requirements provisions of the settlement agreements, Defendants have: (1) fixed, raised, maintained, and/or stabilized the price of AXR Product at supra-competitive levels; and (2) overcharged Plaintiff and other direct purchasers of AXR Product hundreds of millions of dollars by depriving them of the benefits of competition from less-expensive, generic versions of AXR Product. Absent Defendants' illegal scheme as alleged herein, competition in the market would have been greater from the time that Impax entered in October 2009, resulting in lower prices for direct purchasers of AXR Product.

II. JURISDICTION AND VENUE

10. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Plaintiff and members of the Class resulting from violations by the Defendants, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

11. The Defendants named herein are found or transact business within this judicial district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

12. Plaintiff Louisiana Wholesale is a corporation organized under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584.

Louisiana Wholesale purchased AXR Product, purchased under the brand name Adderall XR, directly from Defendant during the Class Period as defined below.

13. Shire LLC is a Kentucky LLC with its principal place of business at 9200 Brookfield Court, Florence, KY 41042-2969. Shire LLC is a successor entity to Shire Laboratories, Inc., a party to the agreements at issue in this case.

14. Shire U.S., Inc. is a Pennsylvania corporation with its principal place of business at 725 Chesterbrook Boulevard, Wayne, PA 19087. Shire U.S., Inc., markets and sells Adderall XR in the United States.

15. Shire is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling Adderall XR throughout the United States.

IV. CLASS ACTION ALLEGATIONS

16. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons who directly purchased AXR Product at any time during the period of October 1, 2009 until the effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

17. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, it is believed to be in excess of fifty (50). Furthermore, the Class is readily identifiable from information and records in the possession of Defendants.

18. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of the Defendants, i.e., they

have paid artificially inflated prices for AXR Product and were deprived of the benefits of competition from less-expensive, generic versions of AXR Product as a result of Defendants' wrongful conduct.

19. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

20. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

21. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

22. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. 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;

c. 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;

d. whether Defendants' actions illegally maintained Defendants' monopoly power in the relevant market;

e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

f. whether, and to what extent, Defendants' conduct caused antitrust injury to

the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

23. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

24. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY AND ECONOMIC BACKGROUND

25. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) a manufacturer who creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

26. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

27. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to

obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an ANDA.

28. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer must prove to the FDA that the generic drug it is taking to market is bioequivalent to the brand-name drug by showing that the same amount of active ingredient is in a patient's blood stream for the same amount of time as the brand drug. A showing of bioequivalence is a scientific demonstration that the generic drug is just as safe and just as effective as the corresponding brand name drug. Generic drugs that demonstrate bioequivalence (and come in the same dosage form and strength, and use the same route of administration, as the corresponding brand drug) are given what is called in the industry an "AB" rating.

29. As a counter-balance, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with what is essentially a preliminary injunction, in the form of a 30-month stay of FDA approval of generic manufacturer's ANDAs.

30. Typically, once approved and on the market, AB-rated generic versions of brand-name drugs are priced significantly below the brand-name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic drugs are rapidly and substantially substituted for their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

31. An "authorized generic" is the brand-name drug product sold under generic trade dress (i.e., generic name and labeling) at a cheaper price than the brand – it is literally the exact same product as made on the same machines as the brand product with the only differences being the name and price. In this case, because no ANDA has been approved for generic Adderall XR, Teva and Impax's AXR Products, although labeled as generic (and referred to as such in media reports), are actually authorized generics manufactured by Shire under its NDA.

32. Although an authorized generic may in some cases be more expensive than an AB-rated generic, it will nonetheless be significantly less expensive than the branded drug. Therefore, authorized generics, like AB-rated generics, are rapidly and substantially substituted for their brand-name counterparts. Likewise, when multiple authorized generics enter the market, prices for these authorized generics may be expected to decrease significantly because of competition among the generic manufacturers, and the loss of sales volume by the branded drug is dramatic. Most importantly, while Teva and Impax's AXR Products are authorized generics, in an unfettered market they would affect the price of other AXR Products in the market in the same way as an AB-rated generic because they were licensed pursuant to arms-length negotiations and compete directly with branded Adderall XR.

33. Generic and authorized generic competition enables direct purchasers to (a) purchase generic versions of brand name drugs at substantially lower prices, and/or (b) purchase the brand name drug at reduced prices. As Shire would have known, with two generic products competing with the brand, the brand's share of the market consistently drops to around 10%.

34. However, until generic manufacturers enter the market with AB-rated or authorized generics, no other product competes with the brand name drug, and therefore, the

brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use various tactics, including the tactics alleged herein, to delay and impede the introduction of AB-rated or authorized generic competition into the market.

35. A person or entity, such as a pharmaceutical company, may file a citizen petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, administrative action. *See* 21 CFR 10.30. Federal regulations provide a 180 day period for the FDA Commissioner to respond to each citizen petition. *See* 21 CFR 10.30(e)(2). However, the FDA frequently takes much longer than 180 days to resolve a citizen petition because reviewing and responding to these petitions is often a resource-intensive and time consuming task because, in addition to its already-existing workload, the FDA must (a) research the citizen petition's subject matter, (b) examine scientific, medical, legal, and sometimes economic issues, (c) consider public responses to the citizen petition, and (d) coordinate internal agency review and clearance of the petition response.

VI. FACTUAL ALLEGATIONS

A. Background

36. On October 11, 2001, the FDA approved Shire's NDA No. 21-303 for marketing and sale of AXR Product under the brand name Adderall XR for the treatment of ADHD. Adderall XR is claimed by three patents: U.S. Patent No. 6,322,819, U.S. Patent No. 6,605,300, and U.S. Patent No. 6,913,768 (collectively the "Adderall XR Patents"). On their face these patents provide exclusivity through 2019.

37. From Shire's launch of Adderall XR in 2001 through September 30, 2011, Shire

realized net sales on Adderall XR of over $6.5 billion. At its height, in 2008, Adderall XR's sales were $1.1 billion, accounting for 47% of Shire's overall revenues that year. Adderall XR has been by far Shire's most successful product, accounting for between 36% and 47% of Shire's business between 2005 and 2009.

1. Shire Faced Competition From Generics Despite Its Patents

38. Despite Shire's various patents that purportedly cover Adderall XR, Shire almost immediately faced the very real possibility of generic competition from a number of generic manufacturers, including Teva and Impax.

39. In November 2002 (only a year after Adderall XR entered the market), Teva filed an ANDA which sought FDA approval to manufacture and sell generic AXR Product in the United States. As part of the Teva ANDA, Teva asserted that the Adderall XR Patents did not block Teva from manufacturing or selling generic AXR Product in the United States. In November 2003 Impax filed an ANDA with the FDA also seeking to enter the market with its own generic AXR Product. Like Teva, Impax asserted that Shire's patents did not block the manufacturing, marketing and sale of its generic product. In response, Shire sued both Teva and Impax for patent infringement under the Hatch-Waxman Act, and in so doing obtained an automatic 30 month stay of FDA approval of the Teva and Impax ANDAs.

40. While these patent suits were pending, Shire's highly-profitable monopoly was at risk because of the danger that: (a) a court might rule that Shire's patents were invalid or not infringed by Teva or Impax's proposed generic products; or (b) the possibility that once the 30 month stay expired, the FDA might approve Teva and Impax's generic products and Teva or Impax might launch their products "at risk" even while the patent lawsuits were pending. Either

event could, and typically does, open the flood gates of generic competition. As Shire would have known, generic competitors would charge substantially less for generic versions of Adderall XR, and once this occurred, Shire would likely lose 90% or more of its sales of AXR Product.

2. Shire Settled Patent Suits Against Teva and Impax

41. In 2006 Shire voluntarily settled its patent suits against both Teva and Impax. The settlements benefitted Shire by ensuring that Teva and Impax would not launch any generic products until April 1, 2009, and October 1, 2009, respectively. At the time of the settlements, Shire faced the risk that had Teva and Impax been able to enter the market in 2006, Shire could potentially lose 90% of its Adderall XR sales, which at the time, were $731 million per year and 46% of Shire's annual business. Through the settlements Shire eliminated the threat from Teva and Impax for 3 years, thereby guaranteeing Shire's monopoly for that period of time. During this period, Adderall XR's sales climbed higher and higher, reaching $1.1 billion in 2008 alone.

42. In return for Teva and Impax's agreement that they would not sell any competing generic products for three years, Shire agreed to facilitate generic competition by eliminating two key barriers that might impede generic competition. First, Shire agreed that after three years it would eliminate any competitive barriers due to the Adderall XR Patents by granting Teva and Impax patent licenses to sell generic AXR Product starting in April 1, 2009, and October 1, 2009, respectively. After the effective dates of their respective agreements, the generics were licensees acting with authority. Accordingly, from the moment the agreements were signed, the patents were taken out of the picture,[2] and this case must be viewed as one in which the patents did not exist as they relate to Teva and Impax. Therefore, this case is about one horizontal competitor

[2] *Cf.* 35 USC § 271 ("whoever without authority" engages in certain conduct infringes the patent).

engaging in anticompetitive conduct by refusing to comply with its voluntary agreement to provide materials that its rivals needed to compete.

43. Second, Shire agreed to eliminate the supply risk that might result if Teva and Impax did not receive FDA approval for their generic products by agreeing to provide Teva and Impax's requirements of AXR Product. In 2006 (and even as of today) Shire has been the only company the FDA has approved to manufacture the AXR Products at issue. As a result, Shire has had complete control over the supply for the product at issue, and it will continue to do so until the FDA approves other companies to make the product. Nevertheless, in exchange for its guaranteed three-year extension to its monopoly, Shire voluntarily agreed to eliminate the competitive barrier created by the generics' need for FDA approval by signing supply contracts in which it agreed to supply all of Teva and Impax's requirements for finished AXR Product for sale under their respective labels.

44. Thus, Shire agreed that in exchange for removing the competitive threat to its monopoly for three years, Shire would not only allow, ***but actually facilitate***, the entry of generic competition into the market, the likely effect of which would be that Shire would cede 90% or more of its monopoly priced Adderall XR sales to lower priced rivals.

a. Impax Settlement

45. In January 2006 Shire and Impax settled their patent litigation (the "Impax Settlement Agreement"). The negotiated settlement included a distribution agreement (the "Impax Distribution Agreement") which provided Impax with a patent license to enter the market in January 2010, unless Shire subsequently settled with Teva, in which case Impax would have a license to enter 181 days after Teva's entry. Because Shire ultimately settled with Teva allowing

Teva to enter the market on April 1, 2009, Impax was allowed to enter the market on October 1, 2009. Under the settlement, Impax agreed not to compete against Shire by selling any generic version of Adderall XR until the agreed-upon entry date.

46. The Impax Distribution Agreement gave Impax the right to purchase all of its requirements for AXR Product from Shire. The Impax Distribution Agreement is a requirements contract – in other words it required that if Impax chose to purchase AXR Product from Shire, Shire was required by the terms of the contract to fill all of Impax's requirements.

47. Because the FDA has not yet approved Impax's ANDA, Impax is (and has been) unable to manufacture its own generic AXR Product. Instead, Impax has elected out of necessity to sell finished AXR Product that Shire provided pursuant to the Impax Distribution Agreement. Except for minor differences in trade dress (such as color or logo), the Shire-supplied AXR Product that Impax sells is identical to branded Adderall XR. Impax, however, sells the product at a substantially lower price.

b. Teva Settlement

48. On August 14, 2006, Shire and Teva settled their patent litigation. The settlement incorporated a license agreement ("Teva License Agreement"), which provided Teva with a patent license that allowed it to enter the market on April 1, 2009. As with the Shire-Impax settlement, the Shire-Teva settlement also provided that Teva had the right to purchase all of its requirements of AXR Product from Shire for the purpose of selling the product as a generic competitor to Adderall XR. The Shire/Teva agreement (like the Impax Distribution Agreement) is a requirements contract, which provided that if Teva chose to purchase its requirements from Shire, Shire was required by the terms of the contract to fill all of Teva's requirements.

49. Because the FDA has not approved Teva's ANDA, Teva elected to order and sell an AXR Product using finished pills purchased from Shire, as provided for in the Teva License Agreement. Teva's AXR Product is manufactured by Shire, same as that sold by Impax. It is the same product as branded Adderall XR, except for differences in trade dress. However, Teva's AXR Product is not sold as Adderall XR but is instead sold by Teva as a generic product. Teva sells the identical product that Shire supplies but at a substantially lower price.

B. Shire Illegally Maintained Its Monopoly for AXR Product

50. As alleged above, in exchange for an extra three years of guaranteed monopoly power Shire agreed that it would help facilitate competition starting in 2009 by eliminating two key barriers that might impede generic competition. Shire did comply with its agreement regarding the first barrier by adhering to the patent licenses that it provided to Teva and Impax. However, Shire intentionally breached in significant part its voluntary agreements to help the generics overcome the second competitive barrier by supplying the generics with the AXR Product that they needed to actively and fully compete.

51. In 2009 (and even as of today) Teva and Impax had not received FDA approval to manufacture their own AXR Products. Since Shire is the only company that has been approved to make the product, there is no source other than Shire from which Teva or Impax could obtain AXR Product to sell in the United States. Consequently, pursuant to the 2006 supply agreements, they elected in 2009 to purchase their requirements from Shire.

52. With two generic products poised to launch in 2009, Shire was faced with likely losing 90% of its Adderall XR sales, which were $1.1 billion in 2008 and constituted nearly 50% of Shire's business. Rather than complying with its agreements and exposing its monopoly to unfettered competition as agreed, Shire unilaterally and intentionally breached the settlement and

distribution agreements. Shire used its position as the sole manufacturer of AXR Product to restrict supply of AXR Product to Teva and Impax in order to harm its rivals and insure that Shire would be able to artificially maintain a significant portion of its monopoly-priced sales that it would have otherwise lost to lower-priced competition.

1. Shire's Refusal To Supply Teva In Violation Of The Shire-Teva Agreement

53. On April 1, 2009, Teva launched its AXR Product in the United States at prices below the prevailing price for branded Adderall XR. In the following months, approximately 60% of total sales of AXR Product shifted from Adderall XR to Teva's less expensive product.

54. On or about July 1, 2009, Teva sent Shire a 12-month forecast as required by the agreements. Included within that forecast was a binding purchase order for the months of October, November, and December 2009.

55. On or about August 28, 2009, Shire told Teva that it would deliver less than the amount of AXR Product Teva requested in the July purchase order. Then, on or about October 2, 2009, Shire told Teva that Shire would not even supply the much-lower levels of product it had told Teva in August that it would deliver.

56. On or about October 5, 2009, a Shire employee, Jeff Cooperrider, admitted to a Teva employee, Jeff Keyser, that Shire was not going to deliver the product it was obligated to supply because Shire's senior management had decided that Shire wanted to keep the product for itself.

57. Shire did in fact breach its agreements with Teva by failing to deliver to Teva the AXR Product requested by Teva in the July purchase order. Shire has continued to breach its agreement by restricting the supply to Teva in October 2009 and thereafter with the purpose and

effect of continuing to hamper Teva's ability and incentive to actively compete.

2. Shire's Refusal To Supply Impax In Violation Of The Shire-Impax Agreement

58. In advance of its entry onto the market on October 1, 2009, Impax notified Shire that Impax intended to rely on Shire to supply Impax's requirements of AXR Product and timely submitted its order for an initial launch quantity. Following its initial order, Impax continued to submit timely orders based on its forecasts.

59. Shire did not timely fill all of Impax's orders specifying delivery in 2009. Shire's failure to meet Impax's orders accelerated in 2010, delivering less AXR Product than ordered in some cases and failing to fill any portion of the order in other cases. These repeated restrictions on Impax's supply in 2010 and 2011 had the purpose and effect of continuing to hamper Impax's ability and incentive to actively compete.

60. According to Impax the effect of Shire's refusal to deal has been that:

> 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.

3. Shire's Supply Restrictions Were Implemented With Anticompetitive Intent

61. Shire's scheme, which included, among other things, refusing to sell its AXR Product to Teva and Impax, was motivated by anticompetitive intent. In refusing to sell AXR Product to Teva and Impax, Shire sacrificed *bona fide* profits (in the form of royalties that it was contractually entitled to receive for such pills) because it calculated that it could earn even more from charging: (a) an immediate monopoly price that it could not have charged absent the supply bottleneck it created; and (b) even greater monopoly prices once its plan was fully in effect.

62. First, Shire was able to immediately charge monopoly prices for the vast majority of the AXR Product that it sold, solely because of the shortage of generic product that Shire intentionally created in breach of its voluntary agreements with Teva and Impax. Absent the supply shortages, the vast majority of purchasers would have bought Teva and Impax's lower-priced products instead of higher-priced Adderall XR. But because the lower-priced products were not available to purchasers due to Shire's refusal-to-sell, purchasers were forced to pay Shire inflated, monopoly prices for branded Adderall XR units. Moreover, once Shire's conduct reduced Teva's and Impax's ability and incentive to price compete, Shire raised its prices (and eliminated discounts and rebates) thereby enabling it to charge: (a) an immediate monopoly price on those sales that it could not have retained absent the supply bottleneck it created; and (b) even greater monopoly prices on such sales once its plan was fully in effect.

63. There was no rational and legitimate business justification for Shire's conduct, and the justification that Shire offered in the Impax breach-of-contract suit was a mere pretext. In that case, Shire asserted: (a) that the shortage of pills was caused by the failure of the Drug Enforcement Administration's ("DEA") to set a high enough quota to manufacture enough pills to

meet demand[3]; and (b) because of the purportedly DEA-created shortage, Shire was allowed under the supply agreements to "fairly" and "reasonably" allocate supply based on the sales that Teva, Impax, and Shire would have obtained through legitimate competition in a market that was not constrained by Shire's conduct.

64. As an initial matter, the DEA has rejected Shire's assertion that the DEA quota created a supply shortage. DEA officials have repeatedly stated that any shortage of pills to sell to generic competitors was not the result of the DEA quota but Shire's unilateral decision to allocate more pills to itself because it wanted to sell more of the expensive brand-name version of this drug. For example, a December 2011 *New York Times* article stated that:

> [DEA] Agent Boggs attributed any supply disruptions to decisions made by manufacturers. Novartis, for instance, makes both branded and generic versions of Ritalin; ***Shire Pharmaceuticals does the same for Adderall XR. In both cases, the companies have ensured that supplies of branded drugs are adequate while allowing generic versions to go wanting.***

Similarly, a January 2012 ABC News piece stated that:

> The DEA questions whether there is actually a shortage of generic supplies, or whether the ***drug companies want to sell more of the expensive brand-name drugs.*** Special Agent Gary Boggs of the DEA's office of diversion control told the New York Times, "[w]e believe there is plenty of supply." Barbara Carreno, a DEA spokeswoman, told Reuters that hundreds of drugs do not require a DEA quota and those shortages are not caused by quota limits, but marketing ploys by drug makers... *"**Any shortage of these products is therefore a result of decisions made by industry regarding manufacturing or distribution.**"*

65. Moreover, even if the DEA quota did create a supply shortage (which was not the case), the supply agreements did not allow Shire to choose how to allocate the pill supply. Also,

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3 The active pharmaceutical ingredient ("API") used to manufacture AXR Product is a controlled substance that is subject to abuse. In order to prevent diversion of AXR Product to the black market, the DEA estimates the number of prescriptions that will be written in the upcoming year and limits the manufacture of the product in line with those estimates. To comply with this quota system, Shire must submit an annual application to the DEA stating how much API it requests for the upcoming year. DEA reviews the application and sets the annual quota based on its prescription estimates.

even if Shire had been contractually allowed to allocate the pill supply (which is not the case), Shire did not act fairly and reasonably in allocating 40-50% of the supply to itself. Shire has asserted that in a market that was not constrained by its refusal to sell, Shire would have naturally gotten 40% of the sales because of various discounts and rebates it offered. In an unconstrained market, Shire would not have retained more than a *de minimus* amount of sales, especially not after Impax entered the market in October 2009.

66. That Shire's explanation is a hollow pretext is evidenced by the fact that after Shire raised Adderall XR prices in late 2010 (thereby reducing, if not eliminating, the supposed justification for keeping 40% of the supply), Shire did not reallocate the supply to Teva and Impax. Instead, even with the increased prices, Shire not only continued to keep 40% of the supply for itself, but actually increased its supply to 50% of the manufactured pills. The foregoing reflects that Shire did not allocate the supply fairly and reasonably, but instead violated the supply agreements it had voluntarily agreed to with the goal of unfairly hampering its rivals so that it could charge artificially-inflated monopoly prices.

4. Shire's Supply Restrictions Resulted in Shire's Illegal Maintenance of Its Power to Charge Monopoly Prices for a Significant Share of AXR Product Sales

67. As alleged above, the generic supply shortfall that Shire created forced purchasers to buy the higher-priced branded Adderall XR. The result was that Shire was able to maintain 40-50% of the market for AXR Product after Teva's and Impax's entry, when normal market forces would have reduced Shire's market share to approximately 10%. Shire's maintenance of 40 - 50% of the AXR Product market was not due to natural brand-generic competition but rather Shire's allocation of 40-50% of the supply of AXR Product to itself.

68. Shire's conduct enabled it to artificially preserve its ability to sell Adderall XR

units at monopoly prices. This is evidenced by the fact that: (a) Shire was able to retain 40-50% of the sales for AXR Products even though Shire charged a significantly higher price than Teva and Impax for the exact same product, all of which was made in Shire's own factories; and (b) Shire was able to charge even higher prices starting in late 2010 without losing any of its market share – indeed, Shire's share of sales actually rose from 40% to 50% even though Shire raised its prices and the generics did not.

69. As a result, in 3Q 2010 Shire reported that Adderall XR sales were up 41% to $99.7 million for the quarter. Shire's sales numbers continued to climb because of the higher prices – Adderall XR revenues were $146.9M in Q2 2011 and $111M the quarter prior. Shire's SEC filing stated, "product sales grew at a faster rate than US prescription demand due to the effect of significantly lower sales deductions (59% in the second quarter of 2011 compared to 74% in the second quarter of 2010) as a percentage of branded gross sales together with the effect of a price increase taken since the second quarter of 2010."

70. Shire's conduct had the additional effect of restraining and limiting Teva and Impax's ability to compete with each other in the market for AXR Product market. In the absence of the Shire-imposed supply constraints described herein, Teva and Impax would have been able to fully and effectively compete in the market, which would have resulted in significantly lower generic AXR Product prices during the Class Period.

VII. EFFECT ON INTERSTATE COMMERCE

71. At all material times, Adderall XR, manufactured and sold by Defendants, was shipped across state lines and sold to customers located outside its state of manufacture.

72. During the relevant time period, in connection with the purchase and sale of

Adderall XR, monies as well as contracts, bills, and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

73. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone communications and commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

VIII. MARKET POWER

74. Direct proof exists that Defendants had monopoly power over the price of Adderall XR and its generic equivalents. Such direct evidence includes, *inter alia*: (a) transactional data showing a significant, non-transitory decline in AXR Product prices immediately upon entry of generic versions of that product that had not previously occurred; and (b) abnormally high price-cost margins enjoyed by Defendants prior to the entry of generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Defendants had monopoly power.

75. Assuming, *arguendo*, that a relevant market needs to be defined, the relevant product market is Adderall XR and its generic equivalents, in all forms and dosage strengths. The relevant geographic market is the United States and its territories. A firm that was the only seller and/or supplier of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Defendants' ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which AXR

Products are prescribed.

76. Through the anticompetitive conduct alleged herein, Defendants were able to profitably charge supra-competitive prices without losing substantial sales, and thus, by definition, maintained monopoly power with respect to AXR Products sold in the United States.

77. Prior to entry into the market of Teva's generic product in April 2009, Defendants' market share in the relevant market was 100%. After market entry by companies with less-expensive generic versions of Adderall XR, Defendants' market share for this drug product declined dramatically in a short period of time. While Shire has not chosen to completely cut off supply to Teva and Impax, because the only two generic competitors in the market depend exclusively on Shire for supply of their products, Shire's control over supply gives it the power to do so, thereby giving it the power to retain 100% of the market share for itself, if it so chose (improperly). Thus, Shire has at all times retained the ability to unilaterally control prices and/or to restrict all competitors' output. Defendants have therefore maintained monopoly power in the relevant market at all pertinent times.

IX. EFFECTS ON COMPETITION

78. Defendants' actions were intended to suppress, rather than promote, competition on the merits, and have had precisely the intended effect.

79. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' unlawful monopolization. Plaintiff and the Class's injuries consist of paying higher prices for AXR Product than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

80. Defendants' exclusionary conduct suppressed the sale of AXR Product in the United States, and unlawfully enabled Defendants to sell AXR Product at artificially inflated prices. But for Defendants' illegal conduct, Teva and Impax would have been able to capture a higher share of the overall market for AXR Product beginning on October 1, 2009.

81. If Teva and Impax had been allowed to compete effectively with Defendants and had therefore captured a greater share of the overall market for AXR Product, as set forth above, Plaintiff and other members of the Class would have substituted more lower-priced generic Adderall XR for the higher-priced brand name Adderall XR for some or all of their requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining AXR Product purchases.

82. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of AXR Product directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their AXR Product requirements. Plaintiff and the other Class members paid prices for AXR Product that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Adderall XR instead of expensive brand-name Adderall XR; (2) Class members paid artificially inflated prices for generic versions of Adderall XR; and/or (3) the price of branded Adderall XR was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

X. VIOLATIONS ALLEGED

COUNT I
Monopolization (15 U.S.C. § 2)

83. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

84. Defendants possess monopoly power over the price of AXR Product, and over the relevant market – Adderall XR and its generic equivalents – in the United States. But for Defendants' exclusionary and anti-competitive scheme, as alleged herein, Defendants would not have been able to maintain its monopoly power over the price of AXR Product, and over the relevant market.

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

86. Defendants' acts were undertaken in bad faith, for the purpose and with the effect of maintaining Defendants' monopoly in the relevant market.

87. Plaintiff and the Class have been injured in their business and property by reason of Defendants' anti-competitive activities. Plaintiff and the Class's injury consists of incurring substantial overcharges, by being caused to pay higher prices for AXR Products than they would have in the absence of Defendants' anti-competitive conduct. Plaintiff and the Class's injury is of

the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

XI. DEMAND FOR JURY

88. Plaintiff demands trial by jury on all issues so triable.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of themselves and the Class, respectfully pray that:

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

(iii) Plaintiff and the Class be awarded three-fold the damages determined to have been sustained by the Class;

(iv) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) Plaintiff and the Class be granted such other, further relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: May 9, 2012

Respectfully submitted,

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