UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

SHIRE LABORATORIES, INC., AND SHIRE LLC, Plaintiffs, v. ANDRX PHARMACEUTICALS, LLC, ANDRX CORPORATION, AND WATSON PHARMACEUTICALS, INC., Defendants.	:	Civil Action No. 06-61699 (WJZ)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY RELIEF

Plaintiffs Shire Laboratories, Inc. and Shire LLC (collectively "Shire"), by their attorneys, for their Complaint, alleges as follows:

Nature of the Action

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act 28 U.S.C. §§ 2201 and 2202. Shire seeks declaratory relief, i.e., declarations that the patents in suit are infringed, injunctive relief precluding infringement, and attorneys' fees.

The Parties

2. Shire Laboratories, Inc. ("Shire Labs") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

3. Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky and has its principal place of business at 9200 Brookfield Ct., Suite 108, Florence, KY 41042. On or about December 15, 2006, Shire Labs merged with and into Shire LLC.

4. Upon information and belief, defendant Andrx Pharmaceuticals, LLC ("Andrx LLC") is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx LLC operates, conducts, and transacts business in Florida and contracts to supply goods and services in Florida. Upon information and belief, Andrx LLC is a wholly-owned subsidiary of Andrx Corporation ("Andrx Corp.").

5. Upon information and belief, defendant Andrx Corp. is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx Corp. operates, conducts, and transacts business in Florida and contracts to supply goods and services in Florida. Upon information and belief, Andrx Corp. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. Upon information and belief, Andrx Corp. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone or through its subsidiaries.

6. Upon information and belief, defendant Watson Pharmaceuticals, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Nevada and has its principal place of business at 311 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson operates, conducts, and transacts business in Florida and contracts to supply goods and services in Florida. Upon information and belief, Watson

manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone or through its subsidiaries.

Jurisdiction and Venue

7. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent Nos. 6,322,819 B1 ("the '819 patent"), and 6,605,300 B1 ("the '300 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Andrx LLC and Andrx Corp. are subject to personal jurisdiction because they are residents of Florida and conduct business in this State. Watson is subject to personal jurisdiction because it conducts business in this State and because its conduct does and would constitute tortious acts committed in this State.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for Approval of New and Generic Drugs

10. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by the Food and Drug Administration ("FDA") – must first file a new drug application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

11. A person wishing to market a generic copy of a pioneering drug that has previously been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application ("ANDA") for the generic version of the drug. In the ANDA,

the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to attain effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(7)(B).

12. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the NDA holder. 21 U.S.C. § 355(j).

13. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may only seek approval for conditions of use that have previously been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

14. No person may market a new drug in the United States without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiff's Approved Adderall XR® Drug

15. Shire LLC is the assignee of the '819 and '300 patents, which are the subject of this civil action, having acquired the patents on or about December 15, 2006, following a merger with Shire Labs. Shire Development Inc. is currently the holder of approved New Drug Application ("NDA") No. 21-303, which was approved by FDA for the manufacture and sale of a pharmaceutical composition containing mixed amphetamine salts for treatment of

Attention Deficit Hyperactivity Disorder ("ADHD"), having acquired the NDA on or about December 1, 2006, from Shire Labs. Shire US Inc. markets and sells this composition in the United States under the trade name Adderall XR®.

16. FDA has listed the '819 and '300 patents in the Orange Book -- formally known as Approved Drug Products With Therapeutic Equivalence Evaluations -- in connection with NDA 21-303.

17. The '819 patent qualifies for listing in the Orange Book in connection with NDA No. 21-303 because it claims a drug product that is the subject of the NDA.

18. The '300 patent qualifies for listing in the Orange Book in connection with NDA No. 21-303 because it claims a pharmaceutical preparation that is the subject of the NDA.

The Andrx ANDA

19. Upon information and belief, Andrx LLC submitted, and Andrx Corp. caused to be submitted, an abbreviated new drug application, Abbreviated New Drug Application ("ANDA") No. 78-436 ("Andrx ANDA"), to FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture and sale of capsules containing mixed amphetamine salts at the 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg strengths.

20. Upon information and belief, Andrx Corp. and Andrx LLC sent Shire Labs (the former NDA holder) a "Patent Certification Under 21 C.F.R. § 319.94 and Notice of Certification or Noninfringement of a Patent Under 21 C.F.R. § 314.95" ("the Notice Letter"). The Notice Letter represented that Andrx LLC had submitted to FDA the Andrx ANDA and purported paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for capsules containing mixed amphetamine salts at the 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg strengths that are

purportedly bioequivalent to Shire's Adderall XR® products. The purpose of the Andrx ANDA and purported paragraph IV certifications was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its capsules containing mixed amphetamine salts before the expiration of the patents listed in the Orange Book for NDA No. 21-303. Hence, Andrx's purpose in submitting the Andrx ANDA is to market its products described therein before expiration of the '819 and '300 patents.

21. The Andrx Notice Letter offered to grant Shire Labs access to certain confidential information in the Andrx ANDA. Shire Labs requested that Andrx LLC and Andrx Corp. provide certain product information on a confidential basis. Although Andrx LLC and Andrx Corp. indicated to Shire Labs that the requested information would be forthcoming, they failed to provide that information before the expiration of the statutory period under 21 U.S.C. § 355(j)(5)(B)(iii).

22. Upon information and belief, Andrx LLC, Andrx Corp and Watson have assisted with, participated in, provided material support to the preparation and submission of, and/or intend to support the further prosecution of the Andrx ANDA.

23. Upon information and belief, if the Andrx ANDA is approved by FDA, Andrx LLC, Andrx Corp. and Watson will manufacture, offer for sale, or sell the products for which approval is sought in ANDA No. 78-436.

24. Upon information and belief, if the Andrx ANDA is approved by FDA, Andrx LLC, Andrx Corp. and Watson will induce or contribute to the manufacture, offer for sale, or sell the products for which approval is sought in ANDA No. 78-436.

COUNT I

(Patent Infringement of the '819 Patent)

25. Shire re-alleges paragraphs 1 through 24 above as fully set forth therein.

26. On November 27, 2001, the United States Patent and Trademark Office duly and legally issued the '819 patent, entitled "Oral Pulsed Drug Delivery System." A true and correct copy of the '819 patent is attached hereto as Exhibit A.

27. The '819 patent discloses and claims, *inter alia,* a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts.

28. Upon information and belief, the submission of the Andrx ANDA to FDA with a paragraph IV certification for the '819 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '819 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Andrx LLC's, Andrx Corp.'s, and Watson's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of the Andrx ANDA would infringe one or more claims of the '819 patent, and Andrx LLC, Andrx Corp., and Watson would be liable jointly and severally as infringers under 35 U.S.C. §§ 271(a) and/or (g).

30. Upon information and belief, Andrx LLC's, Andrx Corp.'s, and Watson's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of the Andrx ANDA would actively induce and contribute to infringement of the '819 patent, and Andrx LLC, Andrx Corp., and Watson jointly and severally would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

31. Andrx LLC, Andrx Corp., and Watson had actual and constructive notice of the '819 patent prior to filing the Andrx ANDA and filed the Andrx ANDA with a baseless paragraph IV certification without adequate justification for claiming the patent to be invalid and non-infringed. In addition, those entities sent a baseless notice of paragraph IV certification to

plaintiff that included a confidential offer of access in support of their claim of non-infringement, but failed to provide the requested information before the expiration of the statutory period under 21 U.S.C. § 355(j)(5)(B)(iii). Andrx LLC's, Andrx Corp.'s, and Watson's conduct in filing the Andrx ANDA and certifying non-infringement has been, and continues to be, willful.

32. Shire will be irreparably harmed if Andrx LLC, Andrx Corp., and Watson are not enjoined from infringing or actively inducing or contributing to infringement of the '819 patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT II

(Patent Infringement of the '300 Patent)

33. Shire re-alleges paragraphs 1 through 24 above as fully set forth therein.

34. On August 12, 2003, the United States Patent and Trademark Office duly and legally issued the '300 patent, entitled "Oral Pulsed Drug Delivery System." A true and correct copy of the '300 patent is attached hereto as Exhibit B.

35. The '300 patent discloses and claims, *inter alia,* a pharmaceutical preparation for the delivery of mixed amphetamine salts.

36. Upon information and belief, the submission of the Andrx ANDA to FDA with a paragraph IV certification for the '300 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '300 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Andrx LLC's, Andrx Corp.'s, and Watson's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of the Andrx ANDA would infringe one or more

claims of the '300 patent, and Andrx LLC, Andrx Corp., and Watson would be liable jointly and severally as infringers under 35 U.S.C. §§ 271(a) and/or (g).

38. Upon information and belief, Andrx LLC's, Andrx Corp.'s, and Watson's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of the Andrx ANDA would actively induce and contribute to infringement of the '300 patent, and Andrx LLC, Andrx Corp., and Watson jointly and severally would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

39. Andrx LLC, Andrx Corp., and Watson had actual and constructive notice of the '300 patent prior to filing the Andrx ANDA and filed the Andrx ANDA with a baseless paragraph IV certification without adequate justification for claiming the patent to be invalid and non-infringed. In addition, those entities sent a baseless notice of paragraph IV certification to plaintiff that included a confidential offer of access in support of their claim of non-infringement, but failed to provide the requested information before the expiration of the statutory period under 21 U.S.C. § 355(j)(5)(B)(iii). Andrx LLC's, Andrx Corp.'s, and Watson's conduct in filing the Andrx ANDA and certifying non-infringement has been, and continues to be, willful.

40. Shire will be irreparably harmed if Andrx LLC, Andrx Corp., and Watson are not enjoined from infringing or actively inducing or contributing to infringement of the '300 patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

Prayer for Relief

WHEREFORE, Shire seeks the following relief:

A. A judgment that Andrx LLC, Andrx Corp., and Watson have infringed the '819 and '300 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that the effective date of any FDA approval of the Andrx ANDA be not earlier than the expiration date of the '819 and '300 patents, including any extensions or regulatory exclusivities appended thereto;

C. A judgment declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the Andrx ANDA would constitute infringement of the '819 and '300 patents, or inducing or contributing to such conduct, by Andrx LLC, Andrx Corp., and Watson pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (g);

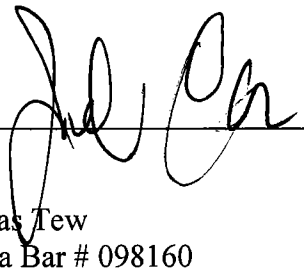
D. A judgment permanently enjoining Andrx LLC, Andrx Corp., Watson, and their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using selling, or offering to sell in the United States, or importing into the United States, the products for which approval is sought in the Andrx ANDA, or any product that infringes or induces or contributes to the infringement of the '819 and '300 patents, until the expiration of those patents, including any extensions or regulatory exclusivities appended thereto;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper

Dated: December 19, 2006

By: 

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