IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

SHIRE LLC,

Plaintiff,

v.

SANDOZ, INC.

Defendant.

COMPLAINT

Plaintiff, Shire LLC ("Shire"), by its attorneys, alleges as follows:

PARTIES

1. Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

2. Upon information and belief, Defendant Sandoz, Inc. ("Sandoz") is a corporation organized and existing under the laws of Colorado, having its principal place of business at 2599 West Midway Boulevard, Broomfield, Colorado 80020.

JURISDICTION AND VENUE

3. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c), 1400(b).

NATURE OF THE ACTION

5. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* Among other things, Shire seeks injunctive relief.

FACTS COMMON TO ALL CLAIMS FOR RELIEF

6. Shire is the holder of New Drug Application ("NDA") No. 21-303, which the Food and Drug Administration ("FDA") approved for the manufacture and sale of pharmaceutical compositions containing mixed amphetamine salts for the treatment of Attention Deficit Hyperactivity Disorder. Shire US Inc. (a related company) markets and sells these compositions in the United States under the trade name Adderall XR®.

7. Upon information and belief, Sandoz reviewed United States Patent No. 6,322,819 ("the '819 patent") and United States Patent No. 6,605,300 ("the '300 patent"), and decided to file an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market generic copies of Adderall XR®.

8. More particularly and upon information and belief, Sandoz filed an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) with the FDA seeking approval to engage in the commercial manufacture, use, and sale of extended-release capsules containing a mixture of four amphetamine salts at dosage strengths of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg.

9. Upon information and belief, the FDA assigned number 78-497 to Sandoz's ANDA for generic copies of Adderall XR®.

10. Sandoz sent Shire a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§§505(j)(2)(B)(ii) [sic] of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" dated

November 29, 2006 ("Sandoz's Notice Letter"), which purported to be a notice of paragraph IV certification according to 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Sandoz's Notice Letter concerns ANDA No. 78-497 and Sandoz's generic copies of Adderall XR®.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '819 PATENT

11. Shire repeats and realleges paragraphs 1 through 10 above.

12. The '819 patent, entitled "Oral Pulsed Dose Drug Delivery System" (Exhibit A), was duly and legally issued on November 27, 2001, to Shire upon assignment from Beth A. Burnside, Xiaodi Guo, Kimberly Fiske, Richard A. Couch, Donald J. Treacy, Rong-Kun Chang, Charlotte McGuinness, and Edward M. Rudnic. The '819 patent concerns a pharmaceutical composition for one or more pharmaceutically active amphetamine salts.

13. Pursuant to 21 U.S.C. § 355(b)(1), the '819 patent appears in "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") as covering Adderall XR®.

14. Upon information and belief, Sandoz's ANDA No. 78-497 includes a paragraph IV certification for the '819 patent to obtain approval to engage in the commercial manufacture, use, or sale of extended-release capsules containing a mixture of four amphetamine salts of 5-, 10-, 15-, 20-, 25-, and 30-mg dosage strengths before the '819 patent expires.

15. Upon information and belief, Sandoz's submission to the FDA of a paragraph IV certification for the '819 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of drug products according to ANDA No. 78-497 before the '819 patent expires constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

16. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of drug products according to ANDA No. 78-497 will infringe one or more claims of the '819 patent.

17. Upon information and belief, Sandoz has been aware of the existence of the '819 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

18. The acts of infringement set forth above will cause Shire to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Shire has no adequate remedy at law and is entitled to preliminary and permanent injunctions prohibiting Sandoz from infringing the '819 patent.

SECOND CLAIM FOR RELIEF
INFRINGEMENT OF THE '300 PATENT

19. Shire repeats and realleges paragraphs 1 through 18 above.

20. The '300 patent, entitled "Oral Pulsed Dose Drug Delivery System" (Exhibit B), was duly and legally issued on August 12, 2003, to Shire upon assignment from Beth A. Burnside, Xiaodi Guo, Kimberly Fiske, Richard A. Couch, Donald J. Treacy, Rong-Kun Chang, Charlotte McGuinness, and Edward M. Rudnic. The '300 patent concerns a pharmaceutical formulation for the delivery of a mixture of amphetamine base salts.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '300 patent appears in the Orange Book as covering Adderall XR®.

22. Upon information and belief, Sandoz's ANDA No. 78-497 includes a paragraph IV certification for the '300 patent to obtain approval to engage in the commercial manufacture, use,

or sale of extended-release capsules containing a mixture of four amphetamine salts of 5-, 10-, 15-, 20-, 25-, and 30-mg dosage strengths before the '300 patent expires.

23. Upon information and belief, Sandoz's submission to the FDA of a paragraph IV certification for the '300 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of drug products according to ANDA No. 78-497 before the '300 patent expires constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of drug products according to ANDA No. 78-497 will infringe one or more claims of the '300 patent.

25. Upon information and belief, Sandoz has been aware of the existence of the '300 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

26. The acts of infringement set forth above will cause Shire to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Shire has no adequate remedy at law and is entitled to preliminary and permanent injunctions prohibiting Sandoz from infringing the '300 patent.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment that Sandoz's submission to the FDA of paragraph IV certifications to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into

the United States of drug products according to ANDA No. 78-497 was an act of infringement of both the '819 and '300 patents;

(b) A judgment that the effective date of approval of any drug product according to ANDA No. 78-497 must be no earlier than the date on which the last of the '819 and '300 patents expire;

(c) A judgment that any drug product according to ANDA No. 78-497 infringes both the '819 and '300 patents;

(d) A judgment that Sandoz's infringement of the '819 and '300 patents was willful;

(e) A judgment preliminarily and permanently enjoining Sandoz and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any drug product according to ANDA No. 78-497 until the expiration of the last of the '819 and '300 patents;

(f) A judgment awarding Shire damages or other monetary relief if Sandoz commercially manufactures, uses, offers to sell, or sells within the United States or imports into the United States any drug product according to ANDA No. 78-497;

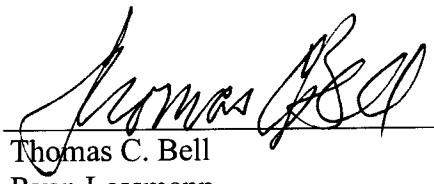
(g) A judgment that this is an exceptional case and awarding Shire its attorneys' fees;

(h) A judgment awarding Shire its costs and expenses;

(i) A judgment awarding Shire pre-judgment and post-judgment interest at the maximum rate allowed by law; and

(j) A judgment awarding Shire such other and further relief as the Court deems just and proper.

Dated: January 26, 2007.

By: 

Thomas C. Bell
Ryan Lessmann
Davis Graham & Stubbs, LLP
1550 Seventeenth Street
Suite 500
Denver, Colorado 80202
(303) 892-9400 (phone)
(303) 893-1379 (fax)

Attorneys for Shire LLC

Of Counsel:
Edgar H. Haug (EH 6243)
Steven M. Amundson (SA 0980)
Porter F. Fleming (PF 1510)
Sandra Kuzmich (SK 5484)
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500