UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

SHIRE LLC,	:	
Plaintiff,	:	
v.	:	**Civil Action No. _____**
COLONY PHARMACEUTICALS, INC., ACTAVIS, INC., and ACTAVIS GROUP hf,	:	
Defendants.	:	

COMPLAINT

Plaintiff, Shire LLC ("Shire"), by its attorneys, 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. §§ 2201-2202. Among other things, Shire seeks declaratory and injunctive relief.

The Parties

2. Shire is a corporation organized and existing under the laws of the State of Kentucky. Shire US Manufacturing Inc., a Maryland corporation with a facility at 11200 Gundry Lane, Owings Mills, MD 21117, manufactures drug products for Shire.

3. Upon information and belief, Defendant Actavis Group hf is an Icelandic company, with its principal place of business at Dalshrauni 1, 220 Hafnarfirdi, Iceland.

4. Upon information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of Delaware. Upon information and belief, Actavis, Inc. is a wholly-owned subsidiary, agent, and alter-ego of Actavis Group hf. Unless otherwise stated, Actavis Group hf and Actavis, Inc. will be collectively referred to as "Actavis."

5. Upon information and belief, Defendant Colony Pharmaceuticals, Inc. ("Colony") is a corporation organized and existing under the laws of Virginia. Upon information and belief, Colony is a wholly-owned subsidiary, agent, and alter-ego of Actavis.

Jurisdiction and Venue

6. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Upon information and belief, Actavis Group hf regularly conducts business throughout the U.S. and specifically within Maryland, including but not limited to Actavis Group hf's direction of the operations and management of Actavis, Inc. and Colony as well as shipping drugs to Actavis, Inc. from locations outside the United States for sales and distribution by Actavis, Inc. within the United States generally and Maryland specifically. Upon information and belief, Actavis, Inc. maintains its "central distribution center" in Columbia, MD.

8. This Court has personal jurisdiction over Actavis Group hf because Actavis Group hf maintains sufficient minimum contacts, both generally and specifically, with Maryland. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

9. Upon information and belief, Actavis, Inc. regularly conducts business throughout the U.S. and specifically derives substantial revenue from goods, food, services, or manufactured products used or consumed in Maryland, including but not limited to the sales and distribution of

drugs. Upon information and belief, Actavis, Inc. maintains three offices within Maryland: one at 7205 Windsor Blvd., Baltimore, MD 21244, a second at 7125 Columbia Gateway Drive, Columbia, MD 21046, and a third at 10065 Red Run Blvd., Owings Mills, MD 21117.

10. This Court has personal jurisdiction over Actavis, Inc. because Actavis, Inc. maintains sufficient minimum contacts, both generally and specifically, with Maryland. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

11. This Court has personal jurisdiction over Colony because, on information and belief, Colony derives substantial revenue from goods, food, services, or manufactured products used or consumed in Maryland. Colony filed the Abbreviated New Drug Application ("ANDA") No. 77-302 in Maryland and delivered a letter pursuant to § 505(j)(2)(B)(ii) regarding such ANDA to Shire Laboratories Inc.'s location at "1550 East Guide [sic] Drive, Rockville, MD 20850" with knowledge that Shire would be injured by such actions in Maryland. On or about December 15, 2006, Shire Laboratories, Inc. merged with and into Shire LLC. Moreover, upon information and belief, Colony intends to sell its infringing product in Maryland. Furthermore, upon information and belief, Colony's finances, policies, and business practices are completely dominated and controlled by Actavis; as such Colony acts as an agent for Actavis. The exercise of such jurisdiction over Colony is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

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

Facts Common to All Claims for Relief

13. Shire is the owner of New Drug Application ("NDA") No. 21-303, which was approved by the Food and Drug Administration ("FDA") 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®.

14. Upon information and belief, Actavis, through one of its wholly-owned subsidiaries, and Colony 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 ANDA seeking approval to market generic copies of Adderall XR®.

15. Upon information and belief, Colony submitted ANDA No. 77-302 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of extended-release capsules containing a mixture of four amphetamine salts at the 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths.

16. Colony sent Shire a letter regarding the '819 and '300 patents pursuant to § 505(j)(2)(B)(ii) dated November 30, 2004 ("Colony's November 2004 Notice Letter"), which states that Colony intends to market its products that are the subject of ANDA 77-302 before the expiration of the '819 and '300 patents. Colony's November 2004 Notice Letter concerns the 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths.

17. Upon information and belief, Actavis, through one of its wholly-owned subsidiaries, directed Colony to file ANDA No. 77-302, and Colony complied. Actavis, through one of its wholly-owned subsidiaries, also directed Colony to submit paragraph IV certifications concerning the '819 and '300 patents for all dosage strengths.

18. Upon information and belief, Actavis, through one of its wholly-owned subsidiaries, and Colony were both aware of the '819 and '300 patents when Actavis, through

one of its wholly-owned subsidiaries, directed Colony to file ANDA No. 77-302 and submit paragraph IV certifications concerning the '819 and '300 patents for all dosage strengths.

19. Upon information and belief, Actavis, through one of its wholly-owned subsidiaries, directed Colony to send Shire the November 2004 Notice Letter.

20. Upon information and belief, Actavis reviewed United States Patent No. 6,913,768 ("the '768 patent"), and decided to maintain Colony's ANDA 77-302 with the FDA seeking approval to market extended-release capsules containing a mixture of four amphetamine salts.

21. Upon information and belief, Actavis and Colony are preparing to have manufactured a significant quantity of Amphetamine Combination Extended Release Capsules.

First Count:
Infringement of the '819 Patent

22. Shire repeats and realleges paragraphs 1 through 21 above.

23. 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.

24. 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®.

25. Upon information and belief, Colony's ANDA No. 77-302 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 for 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths before the '819 patent expires.

26. Upon information and belief, Colony's submission to the FDA, as directed by Actavis through a wholly-owned subsidiary, of 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 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, Colony's commercial manufacture, use, sale, offer for sale, or importation, as directed by Actavis, into the United States of extended-release capsules containing a mixture of four amphetamine salts with 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths will infringe one or more claims of the '819 patent.

28. Upon information and belief, Colony and Actavis have 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.

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

Second Count:
Infringement of the '300 Patent

30. Shire repeats and realleges paragraphs 1 through 21 above.

31. 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.

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

33. Upon information and belief, Colony's ANDA No. 77-302 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 for 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths before the '300 patent expires.

34. Upon information and belief, Colony's submission to the FDA, as directed by Actavis through a wholly-owned subsidiary, of 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).

35. Upon information and belief, Colony's commercial manufacture, use, sale, offer for sale, or importation, as directed by Actavis, into the United States of extended-release capsules containing a mixture of four amphetamine salts with 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths will infringe one or more claims of the '300 patent.

36. Upon information and belief, Colony and Actavis 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.

37. The acts of infringement set forth above will cause Shire to suffer irreparable harm. Colony's and Actavis' infringement will continue unless enjoined by the Court. Shire has

no adequate remedy at law and is entitled to preliminary and permanent injunctions prohibiting Colony and Actavis from infringing the '300 patent.

Third Count:
Infringement of the '768 Patent

38. Shire repeats and realleges paragraphs 1 through 21 above.

39. The '768 patent, entitled "Sustained Release Delivery of Amphetamine Salts" (**Exhibit C**), was duly and legally issued on July 5, 2005, to Shire upon assignment from Richard A. Couch, Beth A. Burnside, and Rong-Kun Chang. The '768 patent concerns a pharmaceutical composition comprising a once-a-day sustained release formulation of at least one or more pharmaceutically active amphetamine salts.

40. Upon information and belief, Actavis and Colony intend to commercially manufacture extended-release capsules containing a mixture of four amphetamine salts with 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths. Upon information and belief, Colony is preparing to have manufactured a significant quantity of Amphetamine Combination Extended Release Capsules.

41. Upon information and belief, Actavis' and Colony's commercial manufacture, use, sale, offer for sale, or importation into the United States of extended-release capsules containing a mixture of four amphetamine salts with 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths will infringe one or more claims of the '768 patent.

42. Upon information and belief, Actavis and Colony have been aware of the existence of the '768 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

43. The acts of infringement set forth above will cause Shire to suffer irreparable harm. Actavis and Colony'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 Actavis and Colony from infringing the '768 patent.

Fourth Count:
Actavis' Inducement of Infringement

44. Shire repeats and realleges paragraphs 1 through 21 above.

45. Upon information and belief, Actavis knowingly induced Colony to infringe the '819, '300, and '768 patents.

46. Upon information and belief, Actavis' induced infringement has been deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Prayer for Relief

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment declaring that Colony's submission to the FDA of paragraph IV certifications to obtain approval for the commercial manufacture, use, or sale in the United States of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg extended-release capsules according to ANDA No. 77-302 was an act of infringement of both the '819 and '300 patents;

(b) A judgment declaring that Actavis' and Colony's commercial manufacturing of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg extended-release capsules according to ANDA No. 77-302 is an act of infringement of the '768 patents;

(c) A judgment declaring that the effective date of any approval of Colony's 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg extended-release capsules according to ANDA No. 77-302 shall be no earlier than the date on which the last of the '819, '300, and '768 patents expire;

(d) A judgment declaring that Actavis' and Colony's infringement of the '819, '300, and '768 patents was willful;

(e) A judgment preliminarily and permanently enjoining Actavis and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of extended-release capsules according to ANDA No. 77-302 until the expiration of the last of the '819, '300, and '768 patents;

(f) A judgment preliminarily and permanently enjoining Colony and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of extended-release capsules according to ANDA No. 77-302 until the expiration of the last of the '819, '300, and '768 patents;

(g) A judgment awarding Shire damages or other monetary relief if Actavis commercially manufactures, uses, offers to sell or sells within the United States or imports into the United States any product that infringes the '819, '300, or '768 patents;

(h) A judgment awarding Shire damages or other monetary relief if Colony commercially manufactures, uses, offers to sell or sells within the United States or imports into the United States any product that infringes the '819, '300, or '768 patents;

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

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

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

Dated: March 20, 2007

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