IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALZA CORPORATION, and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
KREMERS URBAN, LLC, and KUDCO IRELAND, LTD.,	)	
Defendants.	)	

COMPLAINT

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendants, Kremers Urban, LLC ("Kremers Urban") and KUDCO Ireland, Ltd. ("KUDCO Ireland") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the filing by the Defendants of Abbreviated New Drug Application ("ANDA") No. 09-1695 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CONCERTA® prior to the expiration of U.S. Patent Nos. 6,919,373 and 6,930,129.

PARTIES

2. Plaintiff ALZA is a Delaware corporation, having its principal place of business at 700 Eubanks Drive, Vacaville, CA 95688.

3. Plaintiff Ortho-McNeil-Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation, having a place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

4. On information and belief, Defendant Kremers Urban is a Delaware limited liability company, having a principal place of business at 301 Carnegie Center, Suite 300, Princeton, NJ 08540.

5. On information and belief, Defendant KUDCO Ireland is a single member private company existing under the laws of Ireland and having a principal place of business at Shannon Industrial Estate, Shannon, County Clare, Ireland.

6. On information and belief, KUDCO Ireland is a sister corporation of Kremers Urban.

7. On information and belief, KUDCO Ireland and Kremers Urban have officers or directors in common.

8. On information and belief, KUDCO Ireland does not reside or have a place of business in the United States.

JURISDICTION AND VENUE

9. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

10. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware corporation, Plaintiff ALZA, in Delaware. This Court has

personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

12. Personal jurisdiction over Kremers Urban is proper because, on information and belief, as a Delaware limited liability company Kremers Urban resides in the state of Delaware and has purposely availed itself of the privilege of doing business in this State.

13. Kremers Urban has represented to Plaintiffs that jurisdiction and venue for this action in the District of Delaware are proper.

14. Kremers Urban has submitted to the personal jurisdiction of the United States District Court for the District of Delaware at least in *Kremers Urban LLC et al. v. Braintree Laboratories Inc.*, 06-642-SLR.

15. Personal jurisdiction over Kremers Urban is also proper because, on information and belief, Kremers Urban maintains continuous and systematic contacts with the State of Delaware, including the sale and use of Kremers Urban's products in Delaware, so as to reasonably allow jurisdiction to be exercised over it.

16. On information and belief, this Court has personal jurisdiction over Kremers Urban by virtue of, among other things: (1) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

17. KUDCO Ireland has represented to Plaintiffs that jurisdiction and venue for this action in the District of Delaware are proper.

18. On information and belief, personal jurisdiction over KUDCO Ireland is proper because KUDCO Ireland expressly consented to general personal jurisdiction in the State

of Delaware by appointing a Delaware resident as its agent for service of process. On information and belief, personal jurisdiction over KUDCO Ireland is also proper because, to the extent that Kremers Urban acted at the direction of, for the benefit of, or on behalf of KUDCO Ireland, such actions within or directed to the State of Delaware are attributable to KUDCO Ireland.

19. On information and belief, personal jurisdiction over Defendants is proper because by filing ANDA No. 09-1695 for generic methylphenidate hydrochloride extended release tablets, they have committed the tort of patent infringement pursuant to 35 U.S.C. 271(e)(2)(A), and the location of that tort is where the patent holder, ALZA, resides, *i.e.*, in the state of Delaware.

20. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because KUDCO Ireland is an alien, because KUDCO Ireland has designated Kremers Urban as its authorized agent, and because Kremers Urban, and consequently KUDCO Ireland, are subject to personal jurisdiction in this judicial district.

GENERAL ALLEGATIONS

21. On July 19, 2005, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 6,919,373 ("the '373 Patent"). A true and correct copy of the '373 Patent is attached hereto as Exhibit A.

22. On August 16, 2005, the USPTO issued U.S. Patent No. 6,930,129 ("the '129 Patent"). A true and correct copy of the '129 Patent is attached hereto as Exhibit B.

23. ALZA is the current assignee of the '373 and '129 Patents.

24. ALZA manufactures the drug covered by the FDA-approved New Drug Application ("NDA") No. 21-121 and marketed under the registered tradename CONCERTA®,

the active ingredient of which is methylphenidate hydrochloride ("CONCERTA" or "the CONCERTA drug product"), in the United States.

25. Ortho-McNeil-Janssen Pharmaceuticals, Inc. holds NDA No. 21-121 for CONCERTA.

26. Plaintiffs own all rights, title and interest in the '373 and '129 Patents, including all rights needed to bring this action in Plaintiffs' names.

27. CONCERTA is covered by one or more claims of the '373 and '129 Patents, which are listed in connection with CONCERTA in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" CONCERTA. 21 U.S.C. § 355(b)(1).

28. The '373 Patent is directed to a method for treating Attention Deficit Disorder ("ADD") and Attention Deficit Hyperactivity Disorder ("ADHD").

29. The '129 Patent is directed to a method of treating ADD and ADHD.

30. On information and belief, Defendants filed ANDA No. 09-1695 with the FDA seeking approval to market generic copies of all dosage strengths of the CONCERTA drug product prior to the expiration of the '373 and '129 Patents. On information and belief, if ANDA No. 09-1695 is approved by the FDA, Defendants will, prior to the expiration of the '373 and '129 Patents, begin marketing generic copies of all dosage strengths of the CONCERTA drug product for the treatment of ADHD, and doctors and patients will use each of the dosage strengths of Defendants' generic copies of the CONCERTA drug product for the indications marketed by Defendants.

31. Pursuant to FDA regulation 21 C.F.R. § 314.94, each of Defendants' generic copies of CONCERTA's dosage strengths must have the same respective dosage strengths of CONCERTA and must be bioequivalent to CONCERTA.

32. Defendants have asserted to the FDA that their generic copies of CONCERTA's dosage strengths have the same respective dosage strengths and are bioequivalent to CONCERTA.

33. Defendants have represented that the Reference Listed Drug (RLD) of their ANDA No. 09-1695 is NDA No. 21-121, which is the NDA that authorizes the marketing of the drug product CONCERTA in four dosage strengths (*i.e.*, 18 mg, 27 mg, 36 mg and 54 mg).

34. Defendants have represented that they have included in ANDA No. 09-1695 a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '373 and '129 Patents are invalid or will not be infringed by the manufacture, use, or sale of the generic copies of the respective dosage strengths of CONCERTA covered by Defendants' ANDA.

35. Plaintiffs received letters on or about December 1, 2009 (the "notice letter"), purporting to be notices of Defendants' ANDA and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii).

36. A Kremers Urban employee signed the notice letter to ALZA on behalf of KUDCO Ireland.

37. On information and belief, Kremers Urban and KUDCO Ireland jointly made the decision to and did file the above-described ANDA and "Paragraph IV" certifications. On information and belief, Kremers Urban and KUDCO Ireland were necessarily aware of the '373 and '129 Patents when they filed the above-described ANDA and "Paragraph IV" certifications.

38. The notice letter received from Defendants contains representations that the ANDA products do not provide an ascending *in vitro* release rate of methylphenidate for an extended period of time, and upon this basis, Defendants assert that the use of Defendants' drug product would not infringe the claims of the '373 Patent. The letter further represents that the Defendants' drug product, *inter alia*, does not achieve a substantially ascending methylphenidate plasma drug concentration over a time period of about 8 hours after administration, and on this basis, Defendants assert that the use of the Defendants' drug product would not infringe the claims of the '129 Patent.

39. While the notice letter makes representations regarding certain characteristics of the ANDA products, no data associated with testing of the ANDA products were provided with the notice letter, and no samples of the ANDA products were offered or provided for independent testing.

40. After receiving Defendants' notice letter, Plaintiffs engaged in continuous and good faith efforts to obtain a copy of Defendants' ANDA on reasonable terms of confidentiality.

41. Despite Plaintiffs' good faith efforts, Defendants have refused to provide Plaintiffs with their ANDA, including any of the portions specifically requested by Plaintiffs that may describe the *in vitro* and *in vivo* characteristics of the ANDA products. The refusal of Defendants to provide access to ANDA No. 09-1695 on reasonable terms and conditions supports Plaintiffs' reasonable belief that the ANDA products infringe one or more claims of the '373 or '129 patents.

42. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants' filing of an ANDA seeking approval to market their generic copies of the respective dosage strengths of the CONCERTA drug product is an act of infringement of one or more claims of the '373 and '129 Patents entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Defendants' ANDA be a date which

is not earlier than the expiration date of the later of the '373 and '129 Patents, including any extensions of those dates.

43. On information and belief, Defendants did not have an adequate good-faith basis for filing the "Paragraph IV" certification(s) accompanying their ANDA.

44. On May 6, 2009, this Court ordered and adjudged in *Alza Corporation, et al. v. Andrx Pharmaceuticals, L.L.C., et al.*, C.A. 05-642-JJF (the "Andrx Action") that claims 1, 6, and 7 of the '373 Patent are invalid for lack of enablement and would not be infringed by products that were the subject of a different ANDA filed by an unrelated party (Andrx Pharmaceuticals, LLC). This Court also found claims 1, 6, and 7 of the '373 Patent not obvious over prior art cited by the defendants in the Andrx Action, which includes prior art identified by Kremers Urban and KUDCO Ireland in the notice letter.

45. On May 7, 2009, ALZA and McNeil-PPC[1], Inc. appealed the May 6, 2009 judgment in the Andrx Action that claims 1, 6, and 7 of the '373 Patent were invalid for lack of enablement and that those claims were not infringed. No cross-appeal was filed by Andrx Pharmaceuticals, LLC and Andrx Corporation from the judgment that the asserted claims were not obvious. ALZA and McNeil-PPC, Inc. respectfully maintain that this Court erred in holding claims 1, 6, and 7 of the '373 Patent not enabled and not infringed.

46. Given this Court's May 6, 2009 decision and the pending appeal in the Andrx Action, if in this case Defendants request the entry of judgment of invalidity of claims 1, 6 and 7 of the '373 Patent based on the collateral estoppel effect of the May 6, 2009 decision in the Andrx Action, Plaintiffs would have no objection, subject to Plaintiffs' reservation of their right, in this case, to reopen and vacate the judgment and to assert claims 1, 6, and 7 of the '373 Patent under Federal Rule of Civil Procedure 60(b)(5) if and when the U.S. Court of Appeals for the Federal Circuit reverses the May 6, 2009 decision in the Andrx Action.

[1] McNeil-PPC, Inc. was the sole authorized distributor of CONCERTA under the '373 and '129 patents and NDA No. 21-121 at the time.

INFRINGEMENT OF THE '373 AND '129 PATENTS

47. Plaintiffs incorporate and reallege paragraphs 1 through 46 above, as if set forth in full herein.

48. The use of Defendants' ANDA Products are covered by one or more claims in each of the '373 and '129 Patents.

49. Defendants had knowledge of the '373 and '129 Patents when they submitted ANDA No. 09-1695.

50. Defendants' filing of ANDA No. 09-1695 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' ANDA Products before the expiration date of the '373 and '129 Patents is an act of infringement of the '373 and '129 Patents under 35 U.S.C. § 271(e)(2).

51. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Products will infringe one of more claims in each of the '373 and '129 Patents.

52. Upon information and belief, the use of Defendants' ANDA Products in accordance with and as directed by Defendants' proposed labeling for the products will infringe one or more claims in each of the '373 and '129 Patents.

53. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Products with their proposed labeling immediately following approval of ANDA No. 09-1695.

54. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of the '373 and '129 Patents immediately following approval of ANDA No. 09-1695.

55. On information and belief, Defendants know that Defendants' ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '373 and '129 Patents, and that Defendants' ANDA Products and their proposed labeling are not suitable for any substantial noninfringing use.

56. On information and belief, Defendants, including by distributing the ANDA products with their proposed labeling, intend to cause others to perform acts that Defendants know will infringe one or more claims in each of the '373 and 129 patents.

57. The foregoing actions by Defendants constitute, and/or will constitute, direct infringement of the '373 and '129 Patents, active inducement of others to infringe the '373 and '129 Patents, and/or contribution to the infringement by others of the '373 and '129 Patents.

58. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, induce infringement of the '373 and '129 Patents immediately following approval of ANDA No. 09-1695.

59. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, contribute to the infringement of the '373 and '129 Patents immediately following approval of ANDA No. 09-1695.

60. Unless Defendants are enjoined from infringing the '373 and '129 Patents, actively inducing infringement of the '373 and '129 Patents, and/or contributing to the infringement of the '373 and '129 Patents, Plaintiffs will suffer irreparable injury.

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the later expiration date of the '373 and '129 Patents, including any extensions of those dates.

62. Plaintiffs do not have an adequate remedy at law.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment that the '373 and '129 Patents are valid and enforceable;

B. The entry of judgment that the '373 and '129 Patents would be directly infringed by Defendants' ANDA Products, either literally or under the doctrine of equivalents; that submission of ANDA No. 09-1695 is an act of infringement of the '373 and '129 Patents; and that Defendants' making, using, offering to sell, selling, marketing, distributing, or importing Defendants' ANDA Products, or any product that infringes the '373 and '129 Patents, prior to the expiration dates of the '373 and '129 Patents, would infringe, actively induce infringement, and contribute to the infringement of the '373 and '129 Patents;

C. The entry of an order directing the FDA to not approve Defendants' ANDA, or, as the case may be, to change the effective date of approval of Defendants' ANDA, to a date not earlier than the date that the '373 or '129 Patents expire, including any extension of such patents;

D. The entry of a permanent injunction, enjoining Defendants, their officers, directors, agents, servants, employees, successors and assigns, and all others in concert and privity with them, from making, using, offering to sell, selling, marketing, distributing, or importing Defendants' ANDA Products, or any other products not colorably different, that infringe the '373 and '129 Patents, and from inducing or contributing to the infringement of the '373 and '129 Patents, until after the expiration of the '373 and '129 Patents;

E. The entry of judgment that, in view of Defendants' relevant acts, this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action;

F. An award of pre-judgment and post-judgment interest on each and every award;

G. An award of Plaintiffs' costs and expenses in bringing and prosecuting this action; and

H. Such other and further relief as the Court may deem just and proper.

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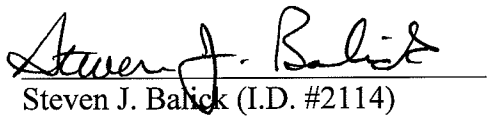

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