IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALZA CORPORATION, and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., Plaintiffs, v. IMPAX LABORATORIES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	Civil Action No. _____

COMPLAINT

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendants, Impax Laboratories, Inc. ("Impax"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (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 Impax of a "major amendment" to Abbreviated New Drug Application ("ANDA") No. 76-535 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 No. 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 Impax Laboratories, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

5. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of Delaware having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

6. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. is a company organized and existing under the laws of Israel with its principal place of business at 5 Basel St. Petach Tikva 49131, Israel.

7. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

8. Teva USA and Teva Ltd. hereinafter are referred to collectively as "Teva."

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, aided, abetted, contributed to and/or participated in the commission of, the 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. This Court has personal jurisdiction over Impax and Teva USA because, on information and belief, as Delaware companies, they reside in the state of Delaware and have purposely availed themselves of the privilege of doing business in this State.

13. This Court further has personal jurisdiction over Impax, because this matter is related to a previous litigation heard before this Court, in which Impax conceded that this Court had personal jurisdiction over it. *See Alza Corporation, et al. v. Andrx Pharmaceuticals, L.L.C., et al.*, C.A. No. 05-642-JJF (D. Del.). This matter also relates to *Alza Corporation, et al. v. Impax Laboratories, Inc., et al.*, C.A. No. 10-1024-LPS (D. Del.), currently stayed, in which Impax again conceded that this Court has personal jurisdiction over it.

14. On information and belief, Teva Ltd., directly or through Teva USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. Such business activities by Teva Ltd. include, but are not limited to, Teva Ltd.'s direction of the operations and management of Teva USA and the shipment of drugs to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and Delaware specifically.

15. On information and belief, Teva USA acts under the direction, control, and influence of Teva Ltd. with respect to, at least, the acts and conduct alleged in this Complaint.

16. Teva USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Teva Ltd., are also attributable to Teva Ltd. for jurisdictional purposes.

17. This Court also has personal jurisdiction over Teva Ltd. by virtue of, among other things, (1) its sale of a substantial volume of prescription drugs in Delaware; (2) its continuous and systematic contacts with Delaware; and (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

18. This Court further has personal jurisdiction over Teva USA, because this matter is related to a litigation pending before this Court, in which Teva USA conceded that this Court had personal jurisdiction over it. *See Alza Corporation, et al. v. Impax Laboratories, Inc., et al.*, C.A. No. 10-1024-LPS.

19. On information and belief, Teva USA and Teva Ltd. have also submitted to the personal jurisdiction of the United States District Court for the District of Delaware at least in *Glaxo Group Limited, et al. v. Teva Pharmaceuticals, et al.*, C.A. No. 02-219-GMS; *Abbott Laboratories, et al. v. Teva Pharmaceuticals, et al.*, C.A. No. 02-1512-SLR; *Glaxo Group Limited, et al. v. Teva Pharmaceuticals USA Inc., et al.*, C.A. No. 03-858-GMS; *Ferring BV v. Teva Pharmaceuticals, et al.*, C.A. No. 04-884-SLR; and *In re: '318 Patent Infringement Litigation*, C.A. No. 05-356-SLR.

20. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

GENERAL ALLEGATIONS

21. On August 16, 2005, the United States Patent and Trademark Office 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 A.

22. ALZA is the current assignee of the '129 Patent.

23. 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.

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

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

26. CONCERTA is covered by one or more claims of the '129 Patent, which is listed in connection with CONCERTA in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as a patent "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).

27. The '129 Patent is directed to a method of treating Attention Deficit Disorder ("ADD") and Attention Deficit Hyperactivity Disorder ("ADHD").

28. On information and belief, Impax filed a "major amendment" to ANDA No. 76-535 with the FDA seeking approval to market generic copies of the 54 mg dosage strength of the CONCERTA drug product prior to the expiration of the '129 Patent.

29. Plaintiffs have sued Defendants for infringement of the '129 Patent in connection with this "major amendment" to ANDA No. 76-535 in this District and that action is presently pending as Civil Action No. 10-1024-LPS.

30. On information and belief, Impax has filed a second "major amendment" to ANDA No. 76-535 with the FDA seeking approval to market generic copies of the 18 mg, 27 mg, and 36 mg dosage strengths of the CONCERTA drug product prior to the expiration of the '129 Patent.

31. On information and belief, if the amended ANDA No. 76-535 is approved by the FDA, Defendants will, prior to the expiration of the '129 Patent, begin marketing generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product for the treatment of ADHD, and doctors and patients will use the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of Defendants' generic copies of the CONCERTA drug product for the indications marketed by Defendants.

32. Pursuant to FDA regulation 21 C.F.R. § 314.94, Impax's generic copies of CONCERTA's 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths must have the same dosage strength of CONCERTA and must be bioequivalent to CONCERTA.

33. Impax has asserted to the FDA that their generic copies of CONCERTA's 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths are bioequivalent to CONCERTA.

34. Impax has represented that the Reference Listed Drug (RLD) of their amended ANDA No. 76-535 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).

35. Impax has represented that they have included in amended ANDA No. 76-535, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '129 Patent is 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 Impax's ANDA.

36. Plaintiffs initially received letters from Impax on or about August 17, 2005, purporting to be the notices of Impax's ANDA and "Paragraph IV" certification(s) required by 21 U.S.C. 355 (j)(2)(B)(i)-(ii).

37. Following receipt of Impax's initial August 2005 Paragraph IV certification(s), Plaintiffs sued Impax for infringement of, *inter alia*, the '129 Patent. *See Alza Corporation, et al. v. Andrx Pharmaceuticals, L.L.C., et al.*, C.A. No. 05-642-JJF.

38. After reviewing Impax's original ANDA No. 76-535, Plaintiffs dismissed their allegations of patent infringement against Impax. Plaintiffs' claims against Impax were dismissed with prejudice on October 10, 2006.

39. On information and belief, the formulation which was the subject of Impax's original ANDA did not meet certain FDA standards for bioequivalency with CONCERTA. Due to "bioequivalence deficiencies," the FDA concluded that Impax's original ANDA was "unacceptable."

40. Plaintiffs received letters on or about October 15, 2010 (the "notice letter"), purporting to be notices of Impax's first "major amendment" to ANDA No. 76-535 and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii).

41. On information and belief, Impax's first "major amendment" to ANDA No. 76-535 relates to a new 54 mg methylphenidate dosage formulation ("Impax's amended ANDA Products") designed to meet certain FDA standards for bioequivalency with CONCERTA that were not met by the original formulation.

42. Plaintiffs received letters on or about March 24, 2011 (the "second notice letter"), purporting to be notices of Impax's second "major amendment" to ANDA No. 76-535 and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii).

43. On information and belief, Impax's second "major amendment" to ANDA No. 76-535 relates to new 18 mg, 27 mg, and 36 mg methylphenidate dosage formulations (also "Impax's amended ANDA Products") designed to meet certain FDA standards for bioequivalency with CONCERTA that were not met by the original formulation.

44. On information and belief, Teva is identified in amended ANDA No. 76-535 as the distributor for Impax's amended ANDA Products.

45. Pursuant to 35 U.S.C. § 271(e)(2)(A), Impax's filing of the amended ANDA seeking approval to market their generic copies of the 18 mg, 27 mg, and 36 mg dosage strengths of the CONCERTA drug product (along with generic copies of the 54 mg dosage strength of CONCERTA) is an act of infringement of one or more claims of the '129 Patent 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 Impax's amended ANDA be a date which is not earlier than the expiration date of the '129 Patent, including any extensions of that date.

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

INFRINGEMENT OF THE '129 PATENT

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

48. The use of Impax's amended ANDA Products are covered by one or more claims in the '129 Patent.

49. Impax had knowledge of the '129 Patent when they submitted the first and second major amendments to ANDA No. 76-535.

50. Impax's filing of amended ANDA No. 76-535 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Impax's amended ANDA Products before the expiration date of the '129 Patent is an act of infringement of the '129 Patent under 35 U.S.C. § 271(e)(2).

51. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Impax's amended ANDA Products will infringe one or more claims in the '129 Patent.

52. Upon information and belief, the use of Impax's amended ANDA Products in accordance with and as directed by Impax's proposed labeling for the products will infringe one or more claims in the '129 Patent.

53. On information and belief, unless enjoined by this Court, Impax and Teva plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Impax's amended ANDA Products with their proposed labeling immediately following approval of amended ANDA No. 76-535.

54. On information and belief, unless enjoined by this Court, Impax and Teva plan and intend to, and will, actively induce infringement of the '129 Patent immediately following approval of amended ANDA No. 76-535.

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

56. On information and belief, Impax and Teva, including by distributing Impax's amended ANDA products with their proposed labeling, intend to cause others to perform acts that Defendants know will infringe one or more claims in the '129 Patent.

57. The foregoing actions by Impax and Teva constitute, and/or will constitute, direct infringement of the '129 Patent, active inducement of others to infringe the '129 Patent, and/or contribute to the infringement by others of the '129 Patent.

58. On information and belief, unless enjoined by this Court, Impax and Teva plan and intend to, and will, induce infringement of the '129 Patent immediately following approval of amended ANDA No. 76-535.

59. On information and belief, unless enjoined by this Court, Impax and Teva plan and intend to, and will, contribute to the infringement of the '129 Patent immediately following approval of amended ANDA No. 76-535.

60. Unless Impax and Teva are enjoined from infringing the '129 Patent, actively inducing infringement of the '129 Patent, and/or contributing to the infringement of the '129 Patent, 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 Impax's amended ANDA to be a date which is not any earlier than the expiration date of the '129 Patent, including any extension of that date.

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 '129 Patent is valid and enforceable;

B. The entry of judgment that the '129 Patent would be directly infringed by Impax's amended ANDA Products, either literally or under the doctrine of equivalents; that submission of amended ANDA No. 76-535 is an act of infringement of the '129 Patent; and that Impax and Teva's making, using, offering to sell, selling, marketing, distributing, and/or importing Impax's amended ANDA Products, or any product that infringes the '129 Patent, prior to the expiration date of the '129 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '129 Patent;

C. The entry of an order directing the FDA to not approve Impax's amended ANDA, or, as the case may be, to change the effective date of approval of Impax's amended ANDA, to a date not earlier than the date that the '129 Patent expires, including any extension of such patent;

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 Impax's amended ANDA Products, or any other products not colorably different, that infringe the '129 Patent, and from inducing or contributing to the infringement of the '129 Patent, until after the expiration of the '129 Patent;

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.

ASHBY & GEDDES

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