IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC., Plaintiffs,	)	
v.	)	Civil Action No. _____
MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	)	

COMPLAINT

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"), 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 Mylan of Abbreviated New Drug Application ("ANDA") No. 206726 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. 8,163,798.

PARTIES

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

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

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a company organized under the laws of the State of West Virginia and has a place of business at 781 Chestnut Ridge Road, P.O. Box 4310, Morgantown, West Virginia 26504-4310.

5. On information and belief, Defendant Mylan Inc. is a company organized under the laws of the Commonwealth of Pennsylvania and has a place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

JURISDICTION AND VENUE

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

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

8. On information and belief, Mylan Pharmaceuticals Inc. formulates, manufactures, packages, markets, distributes, and sells generic pharmaceutical products. On information and belief, those products are marketed, distributed, and sold in the District of Delaware and throughout the United States.

9. On information and belief, Mylan Pharmaceuticals Inc. is the owner of ANDA No. 206726.

10. On information and belief, if the FDA approves ANDA No. 206726, Mylan Pharmaceuticals Inc. will, *inter alia*, manufacture, package, label, perform quality control testing, and perform release and stability testing on the generic products that are the subject of ANDA No. 206726. On information and belief, Mylan Pharmaceuticals Inc. will market, distribute, and/or sell the generic products that are the subject of ANDA No. 206726 in the District of Delaware.

11. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. by virtue of the fact that by filing ANDA No. 206726 for generic methylphenidate hydrochloride

extended-release tablets, Mylan Pharmaceuticals Inc. has, *inter alia*, 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 Mylan Pharmaceuticals Inc. 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 Mylan Pharmaceuticals Inc. is proper because Mylan Pharmaceuticals Inc. is, on information and belief, a corporation registered to do business in Delaware that has purposely availed itself of the privilege of doing business in this State.

13. On information and belief, personal jurisdiction over Mylan Pharmaceuticals Inc. is also proper because Mylan Pharmaceuticals Inc. 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, the registered agent for service for Mylan Pharmaceuticals Inc. is Corporation Service Company, 2711 Centerville Road Suite 400, Wilmington, Delaware 19808.

14. Mylan Pharmaceuticals Inc. has submitted to the personal jurisdiction of the United States District Court for the District of Delaware in numerous actions, such as at least *Forest Laboratories, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 08-52-GMS; *Shionogi Pharma Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 10-135-RBK; *Forest Laboratories, Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-1605-SLR; *Orion Corporation v. Mylan Pharmaceuticals Inc.*, C.A. No. 12-523-GMS; *Santarus, Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-145-RGA; and *Viiv Healthcare Company et al. v. Mylan Inc. and Mylan Pharmaceuticals, Inc.*, C.A. No. 12-1065-RGA.

15. Mylan Pharmaceuticals Inc. has also previously availed itself of this forum for the purpose of litigating a patent dispute in numerous actions, such as at least *Mylan*

Pharmaceuticals Inc. v. Ethypharm S.A., C.A. No. 10-1064-LPS; *Mylan Pharmaceuticals Inc. v. Galderma Laboratories, Inc.*, C.A. No. 10-892-LPS; and *Mylan Pharmaceuticals, Inc. and Mylan Inc. v. Eurand, Inc., et al.*, C.A. 10-306-SLR.

16. Personal jurisdiction over Mylan Pharmaceuticals Inc. is also proper because, on information and belief, Mylan Pharmaceuticals Inc. maintains continuous and systematic contacts with the State of Delaware, including the sale and use of Mylan Pharmaceuticals Inc.'s products in Delaware, so as to reasonably allow jurisdiction to be exercised over it. On information and belief, Mylan Pharmaceuticals Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in Delaware. For example, on information and belief, Mylan Pharmaceuticals Inc. holds current controlled substance "Distributor/Manufacturer" and "Pharmacy – Wholesale" licenses from the State of Delaware. The active ingredient found in the generic drug products that are the subject of ANDA No. 206726 is methylphenidate hydrochloride, a controlled substance.

17. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, among other things: (1) its registration to do business in Delaware; (2) its appointment of a Delaware resident as its agent for service of process; (3) its prior consent to be sued in Delaware; (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes; (5) its systematic and continuous contacts with Delaware; and (6) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm to Plaintiffs in Delaware.

18. On information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc. On information and belief, Mylan Pharmaceuticals Inc. acts as an agent for Mylan Inc. in connection with the sale of pharmaceutical products in the District of Delaware and throughout the United States.

19. On information and belief, Mylan Inc. is a pharmaceutical company that conducts its operations in the District of Delaware and throughout the United States, in part, through Mylan Pharmaceuticals Inc., and together they collaborate in formulating, manufacturing, packaging, distributing, and selling generic drug products in the District of Delaware and throughout the United States.

20. This Court has personal jurisdiction over Mylan Inc. by virtue of the fact, on information and belief, that Mylan Inc. directed, contributed to, and/or supported the filing of ANDA No. 206726 for generic methylphenidate hydrochloride extended-release tablets for the benefit of Mylan Inc. such that Mylan Inc. has, *inter alia*, 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 Mylan Inc. for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

21. Personal jurisdiction over Mylan Inc. is also proper because Mylan Inc. has submitted to the personal jurisdiction of the United States District Court for the District of Delaware in numerous actions, such as at least *Shionogi Pharma Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 10-135-RBK; *Forest Laboratories, Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-1605-SLR; *Santarus, Inc. et al. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-145-RGA; and *Viiv Healthcare Company et al. v. Mylan Inc. and Mylan Pharmaceuticals, Inc.*, C.A. No. 12-1065-RGA.

22. Mylan Inc. has also previously availed itself of this forum for the purpose of litigating a patent dispute in numerous actions, such as at least *Mylan Pharmaceuticals, Inc. and Mylan Inc. v. Eurand, Inc., et al.*, C.A. 10-306-SLR.

23. Personal jurisdiction over Mylan Inc. is also proper because, on information and belief, Mylan Inc. maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it. On information and

belief, Mylan Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors sells and/or distributes a substantial volume of its pharmaceutical products in Delaware.

24. On information and belief, this Court has personal jurisdiction over Mylan Inc. by virtue of, among other things: (1) its presence in Delaware, including through Mylan Pharmaceuticals Inc.; (2) its prior consent to be sued in Delaware; (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes; (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 to Plaintiffs in Delaware.

25. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

GENERAL ALLEGATIONS

26. On April 24, 2012, the USPTO issued U.S. Patent No. 8,163,798 ("the '798 Patent"). A true and correct certified copy of the '798 Patent is attached hereto as Exhibit A.

27. Plaintiffs own all rights, title and interest in the '798 Patent, including all rights needed to bring this action in Plaintiffs' names.

28. ALZA is the current assignee of the '798 Patent.

29. 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.

30. Janssen Pharmaceuticals, Inc. holds NDA No. 21-121 for CONCERTA.

31. Marketing of CONCERTA is authorized in four dosage strengths (*i.e.*, 18 mg, 27 mg, 36 mg and 54 mg) by NDA No. 21-121.

32. CONCERTA is covered by one or more claims of the '798 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. *See* 21 U.S.C. § 355(b)(1).

33. On information and belief, Mylan filed ANDA No. 206726 with the FDA seeking approval to market generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product prior to the expiration of the '798 Patent. On information and belief, if ANDA No. 206726 is approved by the FDA, Mylan will, prior to the expiration of the '798 Patent, begin making, selling, offering for sale, marketing, distributing, and/or importing 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 Mylan's generic copies of the CONCERTA drug product for the indications found in the approved generic label, *i.e.*, the treatment of ADHD.

34. Pursuant to FDA regulation 21 C.F.R. § 314.94, Mylan's generic copies of CONCERTA must have the same dosage strengths as CONCERTA and must be bioequivalent to CONCERTA.

35. Mylan has asserted to the FDA that its generic copies of CONCERTA's 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths have dosage strengths of 18 mg, 27 mg, 36 mg, and 54 mg and are bioequivalent to CONCERTA.

36. Mylan has represented that the Reference Listed Drug (RLD) of its ANDA No. 206726 is CONCERTA.

37. Mylan has represented that it has included in ANDA No. 206726 a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '798 Patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copies of the dosage strengths of CONCERTA covered by Mylan's ANDA No. 206726.

38. On or about April 2, 2014, Plaintiffs received a letter dated April 1, 2014 (the "notice letter"), purporting to be notices of Mylan's ANDA No. 206726 and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). The Paragraph IV certification(s) alleged that the '798 Patent was invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of the products for which FDA approval is sought in ANDA No. 206726.

39. This action is being commenced within forty-five days of the date of the notice letter.

40. On information and belief, Mylan made the decision to and did file ANDA No. 206726 and "Paragraph IV" certification(s).

41. On information and belief, Mylan was necessarily aware of the '798 Patent when it filed ANDA No. 206726 and submitted "Paragraph IV" certification(s) to the FDA in ANDA No. 206726.

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

43. Pursuant to 35 U.S.C. § 271(e)(2)(A), Mylan's filing of an ANDA seeking approval to market generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product is an act of infringement of one or more claims of the '798 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 ANDA No. 206726 be a date which is not earlier than the expiration date of the '798 Patent, including any extensions of that date.

INFRINGEMENT OF THE '798 PATENT

44. Plaintiffs incorporate and reallege paragraphs 1 through 43 above, as if set forth in full herein.

45. The commercial manufacture, use, offer for sale, marketing, distribution, and/or importation into the United States of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product is covered by the '798 Patent.

46. Mylan had knowledge of the '798 Patent when it submitted and filed ANDA No. 206726.

47. Mylan's filing of ANDA No. 206726 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing, and/or importation of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product before the expiration date of the '798 Patent is an act of infringement of the '798 Patent under 35 U.S.C. § 271(e)(2).

48. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product will infringe the '798 Patent.

49. Upon information and belief, the use of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product in accordance with and as directed by the proposed labeling for the products will infringe the '798 Patent.

50. On information and belief, unless enjoined by this Court, Mylan plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product with their proposed labeling immediately following approval of ANDA No. 206726.

51. On information and belief, Mylan knew or was willfully blind to knowing that Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product and their proposed labeling are especially made or adapted for use in infringing the '798 Patent, and that Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product and their proposed labeling are not suitable for any substantial noninfringing use.

52. On information and belief, Mylan, including by making and distributing generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product with their proposed labeling, intends to cause others to perform acts that Mylan knows will infringe the '798 Patent.

53. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, actively induce infringement of the '798 Patent immediately following approval of ANDA No. 206726.

54. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, contribute to the infringement of the '798 Patent immediately following approval of ANDA No. 206726.

55. The foregoing actions by Mylan constitute, and/or will constitute, direct infringement of the '798 Patent, active inducement of others to infringe the '798 Patent, and/or contribution to the infringement by others of the '798 Patent.

56. On information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent.

57. Unless Mylan is enjoined from infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent, Plaintiffs will suffer irreparable injury.

58. 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 Mylan's ANDA No. 206726 to be a date which is not any earlier than the expiration date of the '798 Patent, including any extensions of that date.

59. 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 '798 Patent is valid and enforceable;

B. The entry of judgment that the '798 Patent would be directly infringed by Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product, either literally or under the doctrine of equivalents; that Mylan's submission of ANDA No. 206726 is an act of infringement of the '798 Patent; and that Mylan's making, using, offering to sell, selling, marketing, distributing, or importing Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product, or any product that infringes the '798 Patent, prior to the expiration date of the '798 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '798 Patent;

C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4) directing the FDA to not approve Mylan's ANDA No. 206726, or any product or compound that infringes the '798 Patent, or, as the case may be, to change the effective date of approval of Mylan's ANDA No. 206726 to a date not earlier than the date that the '798 Patent expires, including any extensions of that date;

D. The entry of a permanent injunction, enjoining Mylan, its 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 Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product, or any other products not colorably different, that infringe the '798 Patent, and from inducing or contributing to the infringement of the '798 Patent, until after the expiration of the '798 Patent, including any extensions of that date;

E. Damages or other monetary relief, including prejudgment interest, if Mylan engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of Mylan's generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA drug product, or any other products that infringe the '798 Patent, or the inducement or contribution of the forgoing, prior to the expiration of '798 Patent, including any extensions of that date;

F. The entry of judgment that, in view of Mylan's 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;

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

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

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

ASHBY & GEDDES

Steven J. Balick (#2114)
Tiffany Geyer Lydon (#3950)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashby-geddes.com
tlydon@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs ALZA Corporation and Janssen Pharmaceuticals, Inc.

Of Counsel:

David T. Pritikin
Lisa A. Schneider
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
dpritikin@sidley.com

Jeffrey P. Kushan
Peter S. Choi
James A. High Jr.
Fitz B. Collings
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

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