

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALZA CORPORATION and)
JANSSEN PHARMACEUTICALS, INC.,)

Plaintiffs,)

v.)

OSMOTICA KERESKEDELMI ES)
SZOLGALTATO KFT, OSMOTICA)
PHARMACEUTICAL CORP., and)
NORWICH PHARMACEUTICALS,)
INC.,)

Defendants.)

REDACTED - PUBLIC VERSION

Civil Action No. _____

COMPLAINT

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

Steven J. Balick (#2114)
Tiffany Geyer Lydon (#3950)
Andrew C. Mayo (#5207)
ASHBY & GEDDES
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.*

Dated: June 24, 2013

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendants, Osmotica Kereskedelmi es Szolgaltato Kft, Osmotica Pharmaceutical Corp., and Norwich Pharmaceuticals, Inc. (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. 20-5327 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 Osmotica Kereskedelmi es Szolgaltato Kft ("Osmotica Kft") is a company organized under the laws of Hungary involved in the development and sale of pharmaceutical products in various countries and has a place of business at Berliu u. 47-49. III. ép. I. em, Budapest 1045, Hungary.

5. On information and belief, Osmotica Kft is the owner of ANDA No. 20-5327 and is the ANDA applicant.

6. On information and belief, Defendant Osmotica Pharmaceutical Corp. ("Osmotica Corp.") is a Delaware corporation that manufactures and sells pharmaceutical products in the United States and has a place of business at 1205 Culbreth Drive, Suite 200, Wilmington, North Carolina 28405.

7. On information and belief, Osmotica Corp. is a wholly-owned subsidiary of Osmotica Kft.

8. On information and belief, Osmotica Corp. and Osmotica Kft share certain officers, directors and/or employees.

9. On information and belief, Osmotica Corp. and Osmotica Kft (collectively, "Osmotica") operate together as a single business and present themselves as a cohesive entity. For example, Osmotica Corp.'s website, at <http://www.osmoticausa.com/index.php>, states "Osmotica is an international group of companies with principal operations located in the United States . . . and Osmotica Kft in Hungary." Osmotica Corp.'s website, at <http://www.osmoticausa.com/contact.php>, lists contact information for Osmotica Kft and Osmotica Corp.

10. 



11. On information and belief, Norwich Pharmaceuticals, Inc. is a Delaware corporation and has a place of business at 6826 State Highway 12, Norwich, New York 13815.

12. 



13. 



JURISDICTION AND VENUE

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

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

16. 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.

17. 


18. 


19. 



20. On information and belief, personal jurisdiction over Osmotica Kft is also proper because by filing ANDA No. 20-5327 for generic methylphenidate hydrochloride extended release tablets, it has committed the tort of patent infringement pursuant to 35 U.S.C. §§ 271(b), 271(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.

21. 



22. Personal jurisdiction over Osmotica Corp. is proper because it is, on information and belief, a Delaware corporation that resides in the State of Delaware and has purposely availed itself of the privilege of doing business in this State.

23. On information and belief, personal jurisdiction over Osmotica Corp. is also proper because Osmotica Corp. 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 of Osmotica Corp. is Corporation Service Company, located at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. On information and belief, the registered office of Osmotica Corp. is located at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

24. 


25. On information and belief, this Court has personal jurisdiction over Osmotica Corp. by virtue of, among other things: (1) its incorporation under the laws of Delaware; (2) its designation of a registered agent and registered office in 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.

26. Personal jurisdiction over Defendant Norwich Pharmaceuticals, Inc. is proper because it is, on information and belief, a Delaware corporation that resides in the state of Delaware and has purposely availed itself of the privilege of doing business in this State. For example, on information and belief, Norwich Pharmaceuticals, Inc. holds current controlled substance "Distributor/Manufacturer" and "Pharmacy – Wholesale" licenses from the State of Delaware. The active ingredient found in the drug products that are the subject of ANDA No. 20-5327 is methylphenidate hydrochloride, a controlled substance.

27. On information and belief, personal jurisdiction over Norwich Pharmaceuticals, Inc. is also proper because Norwich 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 Norwich Pharmaceuticals, Inc. is Corporation Service Company, located at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. On information and belief, the registered office for Norwich Pharmaceuticals, Inc. is located at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

28. 


29. On information and belief, this Court has personal jurisdiction over Norwich Pharmaceuticals, Inc. by virtue of, among other things: (1) its incorporation under the laws of Delaware; (2) its purposeful availment of the privilege of doing business in Delaware; (3) its designation of a registered agent and registered office in Delaware; and (4) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

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

GENERAL ALLEGATIONS

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

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

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

34. 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.

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

36. 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.

37. 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).

38. 


39. Pursuant to FDA regulation 21 C.F.R. § 314.94, Defendants' generic copy of CONCERTA must have the same dosage strength as CONCERTA and must be bioequivalent to CONCERTA.

40. Osmotica has asserted to the FDA that the generic copy of CONCERTA's 54 mg dosage strength has a dosage strength of 54 mg and is bioequivalent to CONCERTA.

41. Osmotica has represented that the Reference Listed Drug (RLD) of its ANDA No. 20-5327 is CONCERTA.

42. Osmotica has represented that it has included in ANDA No. 20-5327 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 copy of the dosage strength of CONCERTA covered by Osmotica's ANDA.

43. On or about May 20, 2013, Plaintiffs received a letter dated May 17, 2013 (the "notice letter"), purporting to be notices of Osmotica's ANDA and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). The Paragraph IV certification 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. 20-5327.

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

45. 


46. On information and belief, Osmotica was necessarily aware of the '798 Patent when it filed the above-described ANDA and "Paragraph IV" certifications to the FDA in the above-described ANDA.

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

48. 


49. Norwich Pharmaceuticals, Inc. states on its website at <http://www.norwichpharma.com/about-norwich> that "Over its 125-year history, Norwich has . . . established an unparalleled history of regulatory compliance." On information and belief, Norwich Pharmaceuticals, Inc. was aware of the Orange Book and that drug products are often protected by patents that are listed in the Orange Book.

50. 


INFRINGEMENT OF THE '798 PATENT

51. Plaintiffs incorporate and reallege paragraphs 1 through 50 above, as if set forth in full herein.

52. The use of Defendants' ANDA Product is covered by the '798 Patent.

53. Osmotica had knowledge of the '798 Patent when it submitted and filed ANDA No. 20-5327.

54. 


55. 


56. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product will infringe the '798 Patent.

57. Upon information and belief, the use of Defendants' ANDA Product in accordance with and as directed by the proposed labeling for the products will infringe the '798 Patent.

58. 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 Product with its proposed labeling immediately following approval of ANDA No. 20-5327.

59. On information and belief, Defendants know or were willfully blind to knowing that Defendants' ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '798 Patent, and that Defendants' ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

60. On information and belief, Defendants, including by making and distributing the ANDA Product with its proposed labeling, intend to cause others to perform acts that Defendants know or were willfully blind to knowing will infringe the '798 Patent.

61. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of the '798 Patent immediately following approval of ANDA No. 20-5327.

62. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, contribute to the infringement of the '798 Patent immediately following approval of ANDA No. 20-5327.

63. The foregoing actions by Defendants 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.

64. On information and belief, Defendants acted without a reasonable basis for believing that they 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.

65. Unless Defendants are 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.

66. 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 Osmotica's ANDA to be a date which is not any earlier than the expiration date of the '798 Patent, including any extensions of that dates.

67. 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 Defendants' ANDA Product, either literally or under the doctrine of equivalents; that submission of ANDA No. 20-5327 is an act of infringement of the '798 Patent; and that Defendants' making, using, offering to sell, selling, marketing, distributing, or importing Defendants' ANDA 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;

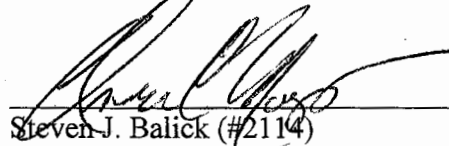
C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4) directing the FDA to not approve ANDA No. 20-5327, or any product or compound that infringes the '798 Patent, or, as the case may be, to change the effective date of approval of Osmotica's ANDA, to a date not earlier than the date that the '798 Patent expires, including any extensions of that date;

D. The entry of a permanent injunction, enjoining 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 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 Defendants engage in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of Defendants' ANDA 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 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;
- 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

Dated: June 24, 2013